University of Alberta

A Comparison of Water and Alcohol in promoting Healing of the Umbilicus and Reducing the Length of Time to Separation of the Umbilical Cord

by

Jennifer Mary Medves

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Nursing

Faculty of Nursing

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled " A Comparison of Water and Alcohol in promoting Healing of the Umbilicus and Reducing the Length of Time to Separation of the Umbilical Cord" submitted by J. M. Medves in partial fulfillment of the requirements for the degree of Master of Nursing.

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Date: September 3, 1996

Dedication

Dedicated to my dearly beloved husband Jay Stuart Medves without whose constant help, support, guidance, and love this thesis would not have been possible.

Abstract

Objectives

The objective was to determine the difference in umbilical cord separation time and skin colonization rates between two randomly assigned groups of term healthy newborn infants.

Methods

A controlled clinical trial consisting of two groups was conducted. Group one had sterile water and group two had sterile alcohol to clean the cord from day of birth to day of cord separation. Umbilical cords were cleaned four times a day. A series of three umbilical swabs were obtained; 1) within three hours of birth, 2) day three, and 3) day of umbilical cord separation. The difference in time to separation was analysed using a t-test. Repeated measures ANOVA was used to compare rates of colonization between groups over time, and Chi-square to compare colonization rates of specific organisms.

Results

Of 148 subjects, 136 (92%) completed the protocol. Cords that were cleaned with sterile water separated quicker than those cleansed with alcohol ($t = 3.15$, $p = .002$). Repeated measures ANOVA to evaluate colonization showed no between group differences ($f = 1.595$, $df = 2$, $p = .205$). Organisms identified on cultures also did not differ between groups. No subject had an umbilical or other infection.

Conclusions

Although no umbilical infection was found, colonization of bacteria is a normal physiological process. Normal healthy neonates do not require routine umbilical cord care. Treatments should be reserved for infants with suspected or confirmed infections.

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Thesis Overview

The purpose of presenting this thesis is to discuss the issue of promoting early umbilical cord separation in the healthy newborn. The overview will provide a background in umbilical cord separation and the working hypothesis within which the investigation took place. The thesis consists of three sections; section one contains the overview, section two the manuscript, and section three the implications for nursing and further research that is required. Appendices follow with short explanations of data not included in the manuscript.

Background

The physiological process of umbilical cord separation in the newborn is poorly understood. Drying, infarction, bacterial contamination and granulocytosis may influence the length of time required for the cord to separate (Wilson, Ochs, Almquist, Dassel, Mauseth, and Ochs, 1985; Rais-Bahrami, Schulte, and Narqvi, 1993). The cord usually separates within the first two weeks of life (Arad, Eyal, and Fainmesser, 1981). Delay in cord separation of longer than three weeks may be associated with polymorphic defects (Abramson, Mills, Sawyer, Regelmann, Nelson, and Quie, 1981). From the moment a normal full term baby is born, the umbilical cord is no longer required for gaseous exchange and nutrition; however, access to a patent umbilical vein and arteries may be of paramount importance for the premature baby.

The normal practice in North America is to ligate the cord with a Hollister® clamp at birth. In the days following birth a variety of treatments are recommended to promote healing and separation of the umbilical cord stump; these treatments vary as does time to

cord separation. The reason for cleaning the cord is two fold; 1) to promote drying and healing, and 2) to prevent infection. The organisms held most responsible for skin infections in the newborn are staphylococcus and streptococcus species. Normal skin flora consists mainly of coagulase-negative staphylococci, of which Staphylococcus epidermidis is the most common. Staphylococcus aureus is the most pathogenic of the staphylococci and the most difficult to treat due to resistance to antibiotics. (Tortora, Funke, and Case, 1992). Concern for infants' health in the past led to the practice of treating the cord with antibacterial solutions in order to prevent neonatal skin infections. Triple dye and or alcohol are used in most institutions in the United States and Canada. Authors of clinical studies (n=16) carried out in the last twenty years have made various recommendations about cord care. Authors of the only Canadian study that was found evaluated the effect of regimes and bacterial colonization, but not time to separation (Paes and Jones, 1987). The researchers concluded that daily applications of triple dye reduced the incidence of bacteria when compared to daily applications of alcohol. Physicians continue to advocate an antibacterial, while nurses and midwives question the practice and recommend a more minimalistic regime. No correlation has been found between the time that the cord is clamped and ligated following delivery and the time of cord separation (Oxford Midwives Research Group, 1991).

At a time when women are being discharged earlier to their homes, an argument can be made to reduce the number and complexity of "treatments" a mother needs to give her newborn. Infants are no longer admitted to newborn nurseries for days at a time. The chance of nosocomial infections has been dramatically reduced with the advent of early

discharge programmes.

Cord care with alcohol seems to be the choice of most Canadian institutions. Alcohol cannot be compared with antibacterial powders such as Sterzac® and Rikospray® as they are not readily available in Canada. Application of alcohol has been associated with a foul odour (Naor et al., 1989), and soft cords (Barr, 1984). If the purpose of cleaning is to speed up drying, then causing the cord to soften would appear to be illogical (Barr, 1984). It has been demonstrated in several studies that water alone promotes healing and separation faster than treatments such as alcohol (Barr, 1984; Bourke, 1990).

The literature review reveals that the umbilical cord separates faster if left dry and intact. Any solution applied to the umbilical cord appears to delay cord separation. The hypothesis to be tested is that minimal cord care promotes faster umbilical cord separation than alcohol.

The purpose of this investigation was to compare sterile alcohol and sterile water as cleaning agents on the newborn cord. In order to counter concerns of colonization differences, swabs were taken from the base of the umbilicus of each baby enrolled in the study at birth, three days of life, and the day that the cord separated. The outcome measure was the number of hours to separation of the cord. Patterns of colonization and a description of organisms isolated are presented alongside the cord separation data.

Conclusion

The process of conducting a clinical trial was an interesting and stimulating experience. As with any clinical trial, more questions have been raised and the process has ensured that I am committed to developing an area of research which will help nurses and midwives care for mothers and their infants in the postnatal period. The manuscript outlines the procedure and results of the clinical trial. The appendices contain short descriptions of several issues that arose as a result of the trial with recommendations as appropriate.

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Umbilical Cord Care : The role of cleaning solutions and bacterial colonization in promoting healing and early separation.

Umbilical Cord Care : The role of cleaning solutions and bacterial colonization in promoting healing and early separation.

The umbilical cord stump dries and separates from the healthy newborn in the first two weeks of life (Arad, Eyal, and Fainmesser, 1981). Physicians and nurses have endeavoured to recommend a solution to clean the cord that will aid separation while at the same time reduce the incidence of umbilical infection (Tötterman and Autio, 1970; Barrett, Mason, and Fleming, 1979; Andrich and Golden, 1984; Schuman and Oksol, 1985; Gladstone, Clapper, Thorp, and Wright, 1988; Salariya and Kowbus, 1988; Mansell, 1990; Meberg and Schøyen, 1990; Verber and Pagan, 1993). As with any cleaning practice, solutions used to clean the cord vary around the world and so does the time to cord separation.

The risk of umbilical infection has been reduced probably as a consequence of early discharge programmes (Barclay, Harrington, Coroy, Royal, and Laforgia, 1994). New parents have many skills to learn in the first few days after delivery and a complicated umbilical cord cleaning regime may well be redundant if the aim is to promote early separation and healing of the umbilicus.

No solution has been shown to maintain a sterile field around the umbilical stump. Colonization of bacteria is thought to aid in the separation process. While the American Academy of Pediatrics has recommended mild soap to clean the skin of babies, most institutions ignore the policy and use a variety of antibacterials both for bathing and to treat the umbilical stump (Martin, Streng, and Miller, 1983). Cord separation maybe delayed by using an antimicrobial agent (Barr, 1984; Bourke, 1990; Barclay et al., 1994;

Ronchera-Oms, Hernádez, and Jimémez, 1994).

The incidence of omphalitis is very small, and the more serious condition of fasciitis even rarer (Samuel, Freeman, Vaishnav, Sajwany, and Nayer, 1994). The requirement to treat the umbilical cord may delay separation and healing. Observation of the area may be more appropriate. No Canadian study could be found that evaluated umbilical cord separation time.

Methods

One hundred and forty eight infants born at a tertiary care hospital in western Canada between 28 May 1996 and 15 July 1996, were included in the study. One hundred and thirty six (91.9%) infants completed the protocol, including one set of twins. Prospective parents' were given an information sheet when they were admitted in active labour (Appendix D). Consent was obtained from the parents within three hours of birth, which was prior to the infants' admission to the newborn nursery. Randomization to groups followed informed written parental consent. Although information sheets and consent forms were offered in five languages [English, French, Spanish, Vietnamese, and Chinese (Appendix D)], the consent forms signed by the parents were all in English, except for one family who signed a Chinese consent form. All infants randomized into the study were at least 37 weeks completed gestation (except one infant who was 36 weeks and 5 days) and assigned apgars of at least 7 at 5 minutes. The families lived within the metropolitan area to ensure that follow up visits could be completed.

Sample Size

Final sample size was determined through power analysis. A difference of 12 hours was considered the least amount of time needed to produce a clinically significant difference in cord separation time. The conventional risks for Type 1 (p=0.05) and Type 11 (beta=0.2) errors were accepted. To meet this criteria, it was determined that a minimum of 50 infants were required for each group. In order to allow for attrition 74 infants were enrolled in each group.

Study Protocol

Prospective parents were given an information sheet by the nurse who admitted them to the case room, or to the pre-admission clinic for elective caesarian section. Parents who wished to participate or who had questions were seen by the principal investigator or her assistant and given a full explanation. The consent form was signed. The parents were given a copy of the consent form that included the pager numbers of the investigators. Randomization took place within three hours of birth using a computer generated blocked random number chart. Each group assignment was concealed in a sealed envelope which was not opened until the consent form was signed. Parents were shown a short video demonstrating cord care.

The first skin swab was taken at the time of randomization to the trial and prior to the first bath. Infants' were bathed in Hibitaine® (chlorhexidine gluconate 2%) within the first six hours of life as hospital policy dictated. The second swab was obtained on day three and this usually took place in the infants' home. Parents' were contacted on the third day by telephone to make an appointment that was acceptable to parents and

researchers.

Parents were asked to page the investigator on the day that the cord separated. At that time the investigator or her assistant made a home visit to confirm cord separation and take a final swab.

Umbilical cord colonization methodology

Three swabs were taken from each infant in the study. A template made of sterile gauze which exposed 5cm by 5cm of skin around the umbilicus was used as a guide to ensure the swabbed area was similar for each infant. Swabs were taken at the base of the cord in a rolled method as advocated in a previously conducted central line catheterisation study (Maki, Ringer, and Alvardo, 1991) (Appendix B). The swabs were placed immediately into transport medium and hand carried to the Clinical Microbiology laboratory at the University of Alberta Hospital. The researcher or assistant inoculated onto blood agar by a rotary movement of the swab an area 2.5cm in diameter at the edge of the plate. The inoculated area was then streaked with a sterile spreader in one movement. The agar plates were incubated at 37°C for between 24 and 48 hours and microbe growth was assessed. The results were recorded and quantified by the same research microbiology technologist. The technologist was blinded to group assignment.

Definitions

Colonization - growth of bacterial organisms to include normal skin flora, coliforms, and mixed fecal flora, as well as potential pathogens such as S. aureus and S. agalactias.

Umbilical cord infection - presence of foul smelling exudate, and/or pus cells, and/or raised and reddened area of skin around the umbilicus.

Sterile Water - sterile water dressing (20cm x 10cm) Kendall.

Sterile Alcohol - Webcor antiseptic isopropyl alcohol pad.

Statistical methods

The SPSS 7.0 statistical package was used to analyse the data. Between group differences in time to umbilical cord separation was calculated using a t-test. The colonization studies were analysed using repeated measures analysis of variance with type of delivery, antibiotics in labour, type of diaper, gender of infant, parity and education of mother as covariates.

Results of Cord Separation Time by Group

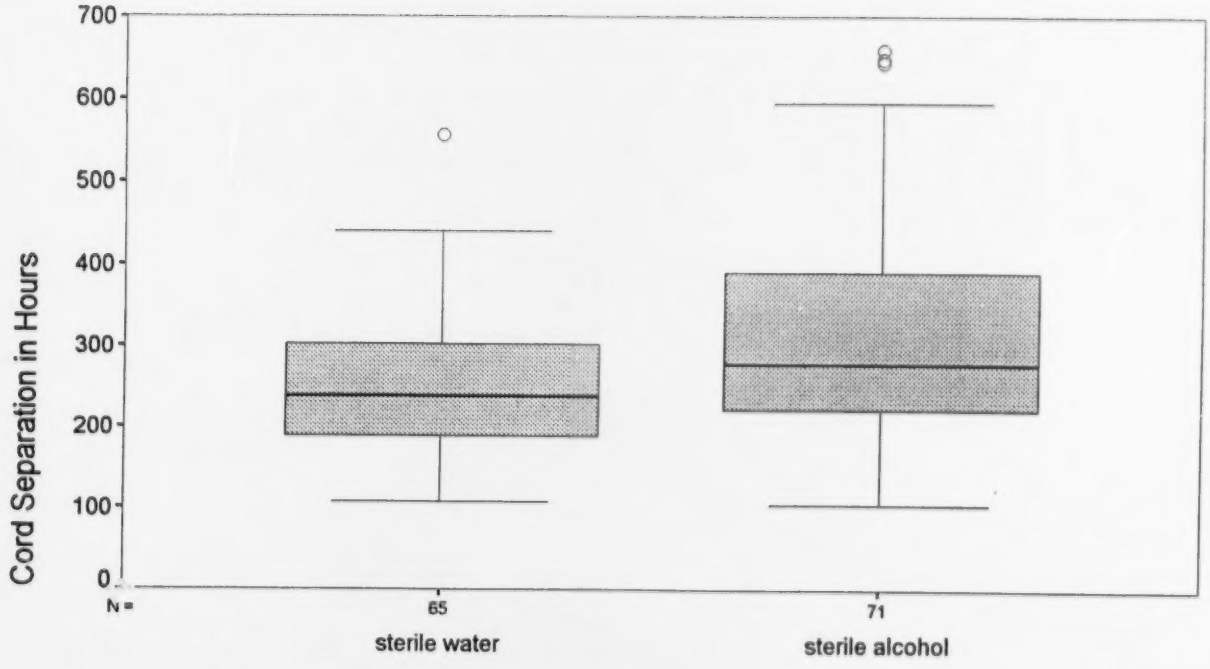
The time to cord separation for the infants' whose cords were cleaned with sterile water was significantly shorter than the cord separation time of the infants' whose cords were cleaned with sterile alcohol ($t = 3.15$, $df = 121$, $p = 0.002$) (Table One). Although the variance differed between groups, normal distribution was assumed because of the large sample size.

Table One : T- tests for Independent Samples of Group Assignment

Variable	Number of cases	Mean in hours	Standard Deviation	Time in Days (SD)
Group One (Sterile Water)	65	252.31	88.89	10.5 (3.7)
Group Two (Sterile Alcohol)	71	313.99	136.17	13.1(5.6)

mean difference = 61.6782 hours

Figure One: Boxplot - Cord Separation by Group



Parents' may not have noticed the exact time of cord separation. However, as the diapers of newborns are changed approximately six times a day, the time of cord separation was accurate within four - six hours for each infant. There would be no reason to suspect that one group would be more diligent than the other in reporting cord separation time. The cord of the twin cleaned with sterile water separated 146 hours (6.1 days) after birth, the cord of the twin cleaned with sterile alcohol separated 170 hours (7.1 days) after birth.

Results of Skin Colonization Studies

Colonization is a function of time. Colonization was assigned values of no growth, small, medium, heavy and very heavy growth. Using repeated measures ANOVA, no differences were found in colonization rates between the two groups ($f = 1.595$, $df = 2$, $p = .205$). However a difference was shown between groups if the third swab is considered alone. The mean growth for the sterile water group was heavy while group two was medium. The designations, while ordinal were treated as interval data because of the manner in which the growth was categorized (appendix B). There was no significant difference between demographic characteristics and either group assignment or colonization except that a higher ratio of boys to girls (60:40) in the group treated with sterile water appeared to be high ($f = .659$, $p = 518$). Multivariate analysis revealed significant interactions between group/gender/gravida/diaper use (f 9.224, df 2, $p < .001$). The findings from the repeated measures ANOVA are presented in Table 2.

Table 2. Repeated measures analysis of variance of colonization rates

	Mean squares	Degrees of freedom	F ratio	p
Time	143.408	2	131.777	.000
Time*Group	1.735	2	1.595	.205
Time*Group*Gravida	3.576	2	3.286	.039
Time*Group*Diaper	5.123	2	4.708	.010
Time*Group*Gender*Gravida*Diaper	10.039	2	9.224	.000

Swab results - day of birth

The first swab was taken prior to the first bath and cleaning. The results serve as a baseline measure. The total number (n=147) of swabs were analysed for quantity and type of culture. In each group slightly over half after culture were sterile (group one 53%, group two 56%). In the remaining specimens mixed flora (one 9%, two 16%); coagulase negative staphylococci (CNS) (one 21%, two 16%); and diptheroids (one 11%, two 9%) were isolated. Analysis of variance of quantity of organisms demonstrated no significant difference ($f = 0.035$, $df = 2$, $p = <.8$) between the two study groups.

Swab results -day three

The second swab was taken in the infants' home (except for infants' delivered by L3CS). Again, between group differences were not found ($f = 2.528$, $df = 2$, $p < .1$). Sterile specimens were obtained from 19% (group one) and 27% (group two). Counts of mixed skin flora and lactose fermenting coliforms appeared to be different between groups.

Swab results - day of separation

The intention was that the final swab (n = 136) would be within 12 hours of cord separation. However 34 infants were swabbed more than 24 hours following cord separation due to parents not informing the research team in time. One specimen had no growth. Mixed skin flora, diptheroids, and coliforms were more prevalent in group one while CNS was more prevalent in group two. Staphylococus aureus was isolated in 32% of group one and 23% of group two. This difference was not significant.

Organisms isolated on culture plates

Chi-square analysis revealed no significant difference in the nominal count of organisms isolated in the three sets of data. Table three lists the count and type of bacterial growth with percentages of plates given as the groups were uneven.

Table Three: Bacterial Colonization by group and time

Organism/ Group	**Group one (sterile water)**	**Group two (sterile alcohol)**	**Group one**	**Group two**	**Group one**	**Group two**
Day of Swab	Day of Birth	Day of Birth	Day 3	Day 3	Separation Day	Separation Day
No growth	39 (53%)	42 (56%)	14 (19%)	20 (27%)	1 (1%)	0
S. aureus	0	0	3 (4%)	1 (1%)	21 (32%)	17 (23%)
S. agalactiae (GBS)	0	0	0	1 (1%)	1 (1%)	4 (2.9%)
Mixed skin flora	7 (9%)	12 (16%)	16 (22%)	8 (11%)	25 (38%)	22 (30.9%)
Mixed fecal flora	0	1 (1%)	2 (2%)	6 (8%)	8 (12%)	6 (8%)
Coliforms-lactose fermenting	0	0	15 (21%)	11 (14%)	25 (38%)	22 (31%)
Coliforms-oxidase negative	0	0	0	3 (4%)	3 (4%)	4 (5%)
Coagulase negative staphlococci	16 (21%)	12 (16%)	28 (39%)	27 (36%)	17 (26%)	28 (39%)
Viridans group streptococci	1 (1%)	1 (1%)	2 (2%)	6 (8%)	1 (1%)	0
Diptheroids	8 (11%)	7 (9%)	1 (1%)	2 (2%)	11 (17%)	6 (8%)
Enterococci	2 (2%)	1 (1%)	10 (14%)	8 (11%)	4 (6%)	2 (2%)

Discussion

Cleaning the cord with alcohol compared to water lengthens the time to umbilical cord separation by 2-3 days, which means that there is a longer time in which a potential port for infection exists. Sterile alcohol compared to sterile water as a cleaning solution did not reduce the level of skin colonization. The length of time to cord separation for the combined data was found to be similar to other North American studies; 10.3 days (Schuman and Oksol, 1983), 15 days (Wilson et al., 1985), 9.8 days (Gladstone et al, 1988), and 10.9 days (Rais-Bahrami et al., 1993). The reason why umbilical cords separate later in North America than umbilical cords in the rest of the world is not easily explained, but frequency of care, duration of hospitization, and humidity may be factors (Wilson et al., 1985).

All the infants in the study were bathed in Hibitaine® (chlorhexidine gluconate 2%) as per hospital policy. Chlorhexidine gluconate has been associated with reduction in colonization of staphylococcus aureus, group B and G streptococci, and Escherichia coli (Bygdeman et al., 1984). Smales (1988) noted that time to cord separation increased from 10 to 20 days when cords were cleaned with 4% chlorhexidine instead of an Iodine preparation . If bacterial contamination is required to assist in cord separation it may well be that the Hibitaine® bath cleansed the newborn skin of the bacteria required for colonization to begin and this may explain why so many specimens obtained on day three had no microbial growth.

Parents are usually asked to keep the cord dry by folding the diaper below the umbilicus until the cord separates and the umbilicus heals. It has been noted that in

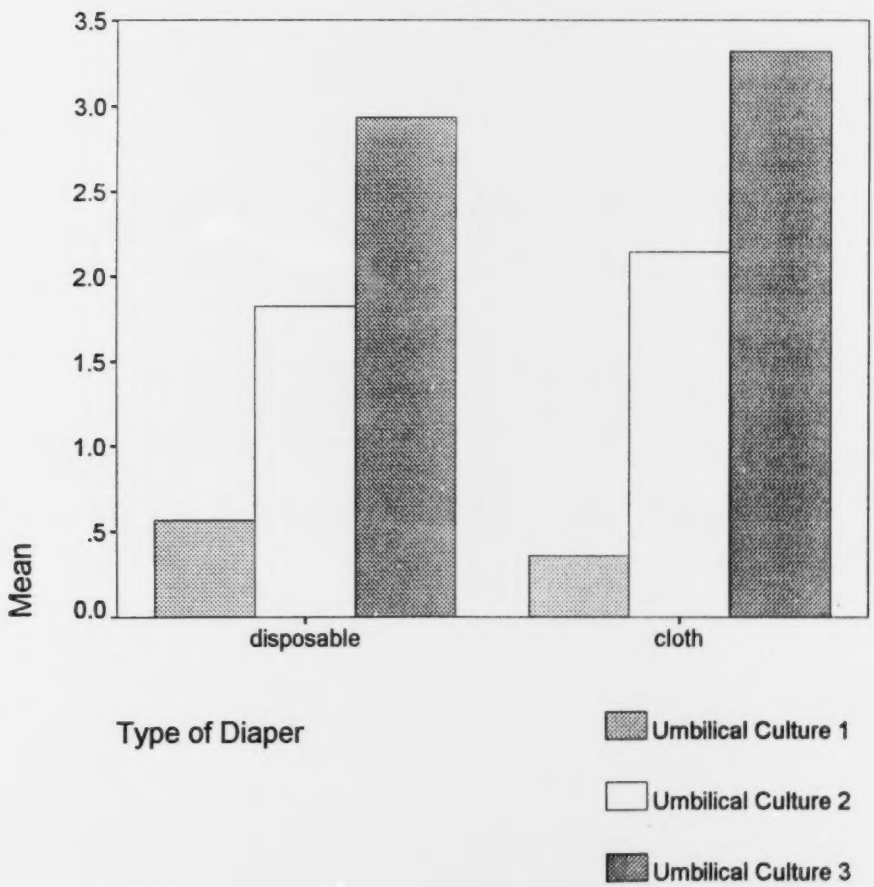
Northern Canada babies are well dressed, even in the summer. This may influence the time to cord separation because the cord is well covered. On several home visits the researchers noted that the babies were over dressed and advised the mother to remove some or all of the clothes.

Another factor to consider is visits by health professionals in the post partum period. In many European countries and Australia, visits by midwives or other health professionals in the first 10 days of life is the norm. In North America more than one home visit in the first 10 days is not common, even with "Healthy Beginnings" programmes. Part of the home visit in England consists of umbilical cord evaluation and while midwives may not actively treat the cord they may apply ligatures. Midwives continue to visit until the cord is separated and the umbilicus is healed. Midwives therefore have an interest in promoting early separation and healing of the umbilicus (Mugford, Somchiwong and Waterhouse, 1986).

The colonization studies revealed expected results. The level of colonization was reduced in the sterile alcohol group but this reduction may have occured by chance. The sterile alcohol did not eradicate any group of organisms (table 3). When repeated measures analysis of variance was used to consider the covariates, interactions were noted between the following groups. Infants of mothers who received antibiotics in labour had less bacterial growth on day three but this difference was not seen by the time the cord separated ($t = 1.55$, $p = .250$). The number of babies born by lower segment caesarian section (LSCS) was small and so statistical analysis is not valid. However, these babies were noted to colonize later than the babies born vaginally.

The sample was divided by cord separation time at 240 hours (10 days) to ascertain if the cords that separated earlier had a difference in colonization rates; no difference was found. Diaper use was the only covariate that was associated with differences in colonization rates (figure 2). Infants' who had cloth diapers throughout had more organisms isolated than infants' who were cared for in disposable diapers following discharge from hospital ($f = 2.303$, $p = .132$).

Figure Two - Mean cultures by time and diaper use



Our findings support the hypothesis that treating the cord with antimicrobial solutions delays umbilical cord separation. As newborns spend limited time in hospital following birth and parents have many adjustments to make, the data shows that routine umbilical cord care should be abandoned. Health care professionals in the community can monitor the progress of separation and intervene as necessary. Colonization of the skin surrounding the umbilicus revealed no significant difference in magnitude, and no type of organism was eradicated by cleaning the cord four times a day with alcohol.

A monetary saving would occur if routine umbilical cord care was discontinued. In terms of nursing time, if 10 minutes is set aside to teach cord care at $22 an hour, $17,600 will be saved at the study hospital which has about 4800 deliveries a year. The unhealed umbilicus is a potential site for infection and so that a delay in time to separation and healing should be avoided.

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Implications For Nursing

A clinical trial allows a researcher to test a hypothesis that has been derived from clinical experience and after a thorough investigation of the literature. The process of the clinical trial is a learning experience especially for a first time researcher. An added bonus has been that funding was provided by the Perinatal Research Centre in order to make this project possible. The research project has several implications for nursing; nursing practice changes, monetary savings, and exposure of research to nurses working on a Labour and Delivery Unit.

The results support our hypothesis that umbilical cords that are cleaned with sterile water separate quicker than umbilical cords cleaned with sterile alcohol. As this project was a thesis at the Master of Nursing level, it was limited in time and quantity of subjects. However, the data showed a statistically significant difference in time to separation. Several authors in the past have recommended that minimalistic cord care is appropriate. It is time to allow the umbilical cord to dry and separate without treatment. The implications for nursing practice are twofold. Nurses can draw on clinical nursing research to reassure parents that the umbilical cord will dry and separate without intervention. In the short time that the mother and baby are in hospital teaching can be concentrated in other areas such as breast feeding.

Administrators can save money by not buying individual bottles of rubbing alcohol for each infant as well as Q-tips. Although the money saved per baby will probably be small, the savings over a year for an entire unit could be substantial. When the infants are discharged home the rubbing alcohol bottles are discarded as are any unused Q-tips

because of the assumed risk of contamination.

A secondary and unanticipated outcome was that the clinical trial was completed in a relatively short period of time - eight weeks - with results that are readily available allows the nurse working at the bedside to evaluate the contribution that research can have for nursing. Several nurses who had shown minimal enthusiasm at the beginning for the project, bought forward several ideas for research that they would like studied. The next step of course is to foster this enthusiasm and encourage them to prepare proposals for research.

Research Projects for the Future

The next step in an area of research can be difficult because many ideas and hypotheses may be found. Umbilical cord separation is of interest in the wider context of Perinatal Comfort Measures. In the beginning this project seemed to be limited to one trial that might support the hypothesis and no further work would be required. A serendipitous finding was the effect of bathing on colonization rates. Nurses should question the routine care given to each mother and baby, especially the first bath and bath demonstration. Nursing care should be individualized with care taking place at the bedside and not in a nursery away from the mother. There are several issues that could be investigated.

1) The issue of bathing babies in chlorhexidine and time to cord separation requires investigation. Chlorhexidine when used as an antimicrobial daily to clean the cord has been found to delay cord separation by as much as 10 days (Smales, 1988). The proposed study would randomize infants to two groups, one group would be

bathed in chlorhexidine and the other group would be bathed using a mild pH balanced soap. The variable of interest would be time to cord separation.

2) An investigation of colonization of GBS on newborns is of interest to nurses, midwives and physicians, however the issue was raised by nursing staff and may constitute a multi-disciplinary study. At this time only the maternal GBS status is known, paternal status would be required as well (appendix C).

3) The requirement and use of the nursery. When money is of key concern to administrators of Health Authorities, the requirement to have a Registered Nurse employed to sit in an almost empty nursery is not efficient. Nurseries are used for re-admissions for phototherapy but this may not be the most appropriate place for phototherapy to take place. With the advent of Labour, Delivery, Post-Partum rooms (LDRP's) the nursery should be redundant. A randomized trial of maternal satisfaction when babies are nursed exclusively at the bedside with one nurse providing all the care compared to the traditional approach is proposed.

Appendix A

Literature review of Umbilical Cord Care Studies and Colonisation Studies

Maternal concerns in treating the cord, colonization and infection associated with the newborn umbilicus, different methods of cord cleaning, and different lengths to cord separation were reviewed. Physicians generally have not been convinced that the problem of infection has been minimised and urge that an antibacterial regime be continued, while midwives and nurses question the rationale and suggest a non interventionist regime may be more appropriate (Barr, 1984, Verber and Pagan, 1993).

A consequence of encouraging women, in the late nineteenth and twentieth centuries, to have their babies in hospital has been the occasional outbreak of infection in nurseries, with sometimes dire consequences (Elias-Jones, Gordon, and Whittaker, 1961; Jellard, 1957). Beginning in the 1960's "rooming-in" has been encouraged and there has been a reduction in infection rates because babies spend their time with their mother and not in large nurseries (Barclay, Harrington, Conroy, Royal, and Laforgia, 1994; Mansell, 1990). With the advent of even shorter stays in hospital for women and their newborns, the risk of cross-infection and acquisition of nosocomial infections has been reduced. At a time in England when many babies were born at home, Elias-Jones and associates (1961) noted that babies born at home did not colonize organisms at the same rate as babies born in hospital, and recommended that women confined to hospital for delivery be transferred home for post partum care.

With shorter institutional stays it may be time to stop treating the umbilical cord and allow nature to take its course. As early as 1980 midwives recognised that changing

the solution to clean the cord resulted in a delay in cord separation (Magowan, Andrews, Pinder, and Allen, 1980). The seminal piece of research was a study by Barr (1984) who concluded that cleaning with alcohol delayed cord separation. In countries such as the United Kingdom and Australia where midwives visit mothers and their newborns until the cord separates and the umbilicus is clean and dry, delay in separation has significant monetary implications. Mugford, Somchiwong, and Waterhouse (1986) demonstrated that a delay in cord separation times required an extra full-time community midwife for every 3000 births per year.

Cleaning Solutions

The American Academy of Pediatrics (1974) recognized the many different methods of cleaning umbilical cords and bathing, and recommended the use of minimal non-toxic and non-abrasive neutral methods. Many American hospitals apply one of the following preparations around and to babies unseparated cords: pHisohex®, betadine, Dial soap®, Hibiclens®, Baby Magic®, Gammophen®, and Mennen's baby lotion®. Cord care regimes also included triple dye, alcohol, iodophor, and bacitracin ointment. However the recommendation for neutral solutions is ignored in many institutions (Martin, Streng, and Miller, 1983).

Perry (1982) reminded nurses and midwives that any umbilical cord care practice must take into account the particular cultural beliefs of a mother. Perry continued that health care professionals should ensure that the new parents are cognizant of the cleaning regime. Naor, Merlob, Litwin and Wielunsky (1989) reported a repulsive odour associated with cleaning the cord with alcohol.

Alcohol has been implicated in a case of neonatal intoxication that occurred when isopropyl alcohol was absorbed through the umbilical area. A moribund male infant, aged three weeks, was admitted to a paediatric unit. The infant slowly regained consciousness and all the tests conducted in the first couple of days gave no indication of the cause of his malaise. Several days later drug screening revealed high levels of blood alcohol, which, when repeated, were negligible. The mother was questioned carefully and she described liberally dosing the cord with alcohol and then applying a binder to the abdomen. The baby was discharged without any lasting effect from the presumptive alcohol intoxication. (Vivier, Lewander, Martin, and Linakis, 1994).

Povidone-iodine has been used to clean cords, but the danger of raised thyroid stimulating hormone (TSH) has lead to this practice being discouraged. Lin, Chen, and Wu (1994) studied the incidence of elevated TSH levels and were able to distinguish the false positives as being among the group of infants who had povidone-iodine solution as cord care. Hypothyroidism is screened routinely around the world with the tests for phenylketonuria, galactosaemia, and glucose-6-phosphate dehydrogenase deficiency. The authors conclude that iodine based solutions should be avoided in umbilical cord care of the newborn.

Soap used for the infants' first bath is usually a matter of hospital policy. Although the American Academy of Pediatrics may have requested a mild nonmedicated soap, many institutions have continued to use concentrated soap (more appropriate for surgical scrubs) as the product of choice. Chlorhexidine has been assessed in several studies on skin colonization patterns (Alder, Burman, Simpson, Fysh, and Gillespie, 1980;

Bygdeman, Hambraeus, Henningson, Nyström, Skoglund, and Tunell, 1984; and Smales, 1988). Alder et al. (1980), in a British study, concluded chlorhexidine powder was associated with low levels of colonization of Staphylococcus aureus, and therefore recommended the use of chlorhexidine powder as an antibacterial agent for newborns. Authors of a Swedish study investigated alcohol with and without chlorhexidine; the combination of solutions resulted in reduced colonization of s. aureus, group B and G streptococci, and E. coli (Bygdeman et al., 1984). Smales (1988) compared 4% chlorhexidine and Iodosan® (an iodine preparation in 70% surgical spirit), and reported fewer infections in the chlorhexidine group. Of particular note, the cord separation time dramatically increased from a mean of 10 days to 20 days when chlorhexidine was used.

The practice of burning granulomas left behind after cord separation is not without danger. Chamberlain, Gorman, and Young (1992) reported three cases of infants seen in the emergency department with chemical burns sustained after silver nitrate 70% concentrate had been applied to the granuloma left after cord separation. The authors caution the use of concentrated silver nitrate especially in unskilled hands.

Separation in time in days

Time of umbilical cord separation varies throughout the world. Researchers report that cord separation appears to take longer in North America than Europe, Australia and India. Authors presented the findings of an in vitro study of different umbilical cord care regimens on drying and antimicrobial effect. The drying effect (weight loss 88%) occurs within the first 3 days (Jeng, Soong, Lau, Chen, and Hwang, 1994). The reason for differences in time from birth to cord separation may be due, in part

to the type of treatment recommended to enhance cord separation and minimize infection (Barr, 1984; Bhalla, Nafis, Rohatgi, and Singh, 1975). Table 4 summarizes the days from birth to cord separation.

Table 4 - Time in Days to Umbilical Cord Separation

Country of Study	Authors	Days to separation	Standard Deviation	Number in Study
Finland (1970)	Tötterman and Autio	6.3	not specified	600
India (1975)	Bhalla et al.	5.8	not specified	840
Israel (1981)	Arad et al.	6.4	0.3	121
N. Ireland (1982)	Barr	6.2	not specified	117
United States (1983)	Schuman and Oksol	10.3	3.3	88
United States (1985)	Wilson et al.	15.0	7.2	245
Holland (1986)	Oudesluys-Murphy et al.	6.0	2.1	279
United States (1988)	Gladstone et al.	9.8	0.5	271
Israel (1989)	Naor et al	6.36	2.64	394
Norway (1990)	Meberg and Schøyen	6.0	2.1	2441
Australia (1990)	Bourke	6.4	not specified	103
United States (1993)	Rais-Bahrami et al.	10.9	4.5	189
Australia (1994)	Barclay et al.	8.9	3.5	890

Caesarian Section may result in a delay in umbilical cord separation time (Rais-Bahrami et al., 1993; Novack, Mueller, and Ochs, 1988). This may be due, in part, to a delay in colonization of the skin by normal vaginal bacterial flora ("Standard umbilical cord," 1994).

Colonization and Infections

S. aureus and group B β-hemolytic streptococci are the organisms most often cited as responsible for neonatal umbilical infections (Elias-Jones et al.,1961; Gooch and Britt, 1978; Jellard, 1957; Meberg and Schøyen, 1985; Paes and Jones, 1987; Pildes, Ramurthy, and Vidyasgar, 1973; Speck, Driscoll, Polin, O'Neill, and Rosenkrantz, 1977; Wald, Merrill, Snyder, and Gutberlet, 1977; and Watkinson and Dyas, 1992). Physicians and medical researchers have therefore recommended 'treating' the umbilical cord in order to reduce the incidence of colonization and infection (Tötterman and Autio, 1970; Andrich and Golden, 1984). Cords that colonized detached earlier than cords that did not colonize (Ronchera-Oms et al. 1994). Colonization rates varied in different studies and have been used in many hospitals to maintain a low colonization rate of S. aureus (Pildes et al. 1973). However, colonization rates do not indicate a potential or actual outbreak of infection (Gooch and Britt, 1978).

Serious Infections and Necrotizing Fasciitis

Occasionally umbilical cord separation had been delayed over three weeks and this may be associated with polymorphic neutrophil defects (Hayward, Leonard, Wood, Harvey, Greenwood, and Soothill, 1979; Abramson et al. 1981). Novack and Associates (1988) suggest that these babies should be followed for at least a year to determine the

proportion of infants with delay in separation that subsequently develop neutrophil problems. A potentially lethal complication of delayed separation and infection can be necrotizing fasciitis, which is a rare complication of omphalitis (Samuel, Freeman, Vaishnav, Sajwany, and Nayar, 1994). The rate of omphalitis in the developing world was not found but omphalitis in the developed world is very uncommon and is associated with prematurity and septic home deliveries (Güvenç et al., 1991). During a ten year study in Washington State, 32 infants were admitted to a hospital with uncomplicated omphalitis, none had a delay in cord separation, and all were treated successfully. At the same hospital, 7 other babies, 6 of whom had complicated omphalitis, developed necrotizing fasciitis with a 71% death rate (Sawin, Schaller, Tapper, Morgan, and Cahill, 1994). Chamberlain (1992) states that an emergency department in a children's hospital in Washington, District of Columbia, that had 57,000 visits and 11,500 admissions annually, only 28 infants had been treated for omphalitis over a 10 year period. Chamberlain does not define the normal method of cleaning the cord but states that antibacterial preparations are used in most American institutions.

Design of studies

The absence of colonization studies in cord care methodology studies has been criticized (Watkinson and Dyas, 1992; Russell, 1995). Randomized studies are few and do not reflect the practice of early discharge home (Barrett et al., 1979; Arad et al., 1981; Mugford et al., 1986). Most studies were convenience samples (Lawrence, 1982; Andrich and Golden, 1984; Barr, 1984; Naor et al., 1989; Mansell, 1990; Bourke, 1990; Barclay et al., 1994). Antiseptic solutions are widely used to reduce the bacterial

colonization but delay cord separation (Bourke, 1990; Ronchera-Oms, Hernández, and Jimémez, 1994; Verber and Pagan, 1993). Infants who are admitted to neonatal units may have to have different cord care regimes because they are at added risk for nosocomial infection. English researchers have recommended the continued use of Sterzac powder (Bain, 1994); and Australia researchers have recommended that alcohol or chlorhexidine be used in the neonatal intensive care setting (Yu, 1990).

Umbilical Cord Care Cleaning Studies

Sixteen studies were found that compared different cleaning regimes. In studies where water was used, separation time of cords cleaned with water was shorter (Barr, 1984; Salariya and Kowbus, 1988; Bourke, 1990; Watkinson and Dyas, 1992; Barclay et al., 1994). Bacitracin ointment caused delay in separation (Arad, Eyal, and Fainmesser, 1981; Andrich and Golden, 1984; Gladstone, Clapper, Thorp, and Wright, 1988). Antibacterial powders such as Cordocel® produced faster separation than solutions (Lawrence, 1982; Mugford et al., 1986; Verber and Pagan, 1993). Cords cleaned with alcohol separated quicker than triple dye (Schuman and Oksol, 1985; Gladstone et al., 1988).

Table 5 - Different Cleaning Regimes

Author	**Treatments compared**	**Recommended**
Arad et al. (1981)	Triple dye/Bactricin ointment	Triple dye
Lawrence (1982)	Sterzac/ Sterets and Sterzac	Sterzac
Andrich and Golden (1984)	Triple dye/ Bactricin ointment	Triple dye
Barr (1984)	Alcohol swabs/water	Water
Schuman and Oksol (1985)	Alcohol/triple dye	Alcohol
Mugford et al. (1986)	Alcohol/Sterzac/ Cordocel/starch/water	Powder
Salariya and Kowbus (1988)	no treatment/alcohol	no treatment
Gladstone et al. (1988)	triple dye/alcohol/ povidone-iodine/ silver sulfadiazine/ bacitracin	povidone-iodine
Naor et al. (1989)	Alcohol/Rikospray	no difference
Meberg and Schøyen (1990)	Sorbact/ chlorhexidine soln.	equal in time to separation
Bourke (1990)	Water/ alcohol	Water
Mansell (1990)	Methylated spirits/ chlorhexidine soln.	Methylated spirits
Watkinson and Dyas (1992)	Alcohol/water/ hexachlorophane	Water
Verber and Pagan (1993)	Chlorhexidine soln/ hexachlorophane	Hexachlorophane
Ronchera-Oms et al. (1994)	Ethanol/ eosin/ chlorhexidine/ iodine	Further study required
Barclay et al. (1994)	Water/ chlorhexidine in water	water

Evaluation of Treatment Studies to Separation Studies

Studies included in Table 2 were evaluated in relation to methodology, subjects, statistical tests, sample size, and implications for practice. The studies are presented in chronological order.

Arad, Eyal and Fainmesser (1981) compared Triple dye, 1% Neomycin, 1% Silver Sulphadiazine ointment, and Bismuth Subgallate. Cords treated with Triple dye and Bismuth Subgallate, an astringent powder, separated earlier than the other two. Participants (n=121) were randomized; with 25 infants in the smallest group (Silver Sulphadiazine). Each group was divided into sub groups to compare delivery type and time of separation. A discussion of the differences is not given although the mean and standard deviation for each group is presented. The most significant difference is in the 1% Neomycin group (n=9). The caesarian delivery group had a mean of 13.1 days (standard deviation (SD) 1.6) until cord separation, while the vaginal delivery group (n=17), had a mean of 11.3, (SD 1.0). These findings are clinically significant in that the difference is 1.8 days.

Lawrence (1982) began an investigation because student midwives noted that the cords of babies in the Special Care Baby Unit (SCBU) separated faster than the cords of babies on the postnatal wards. One group (n=100) had Sterzac powder dusted onto the cord at each diaper change; the second group (n=100) was swabbed with a Steret and then dusted with Sterzac powder. The group treated with Sterzac powder only had a faster rate of separation. The study was carried out in 1979 when babies routinely stayed in hospital for a week, and so the results had a clinically significant effect on the workload of

community midwives. There was a monetary saving as the midwives stopped using Sterets.

Andrich and Golden (1984) conducted a retrospective study at Naval Hospital, Bethesda, Maryland, to compare the incidence of neonatal infections and colonization of the umbilical area. Time of separation was not studied. Following a chart review, infections were noted to have occurred during the first 30 days of life. Bacitracin ointment was used twice a day from May 1978 to September 1980 while the infants were in hospital (n=1229). Triple dye was used twice a day from October 1980 to May 1982 (n=1173). Skin swabs were obtained on the day of discharge which was normally Day 3 for normal deliveries and Day 5 for Caesarian Sections. The colonization rate was significantly higher in the group that was treated with Bactricin ointment. The authors conclude that Triple dye reduces the incidence of *Staphylococcus aureus* colonization and recommended using Triple dye for cord care.

Barr (1984) studied 117 babies in two uneven groups. The treatment group used Steret® swabs and Cicatrin® powder (n=83). Of these 14 babies had an application of copper sulphate for granulated umbilical tissue. The control group (n=34) babies had no treatment to their cords, and 3 had copper sulphate applications. The mean time to cord separation was not stated. In the treatment group, 44 out of 83 cords separated by Day 7, and one quarter were not separated until day 14. In the non treatment group, 28 out of 34 separated by Day 7 and all were healed by Day 10. Barr notes that the mothers seemed much happier if they did not have to perform cord care.

Schuman and Oksol (1985) conducted a study at the USAF hospital in Grand Forks, North Dakota. Group1 (n=71) received Triple dye at every diaper change; group 2 (n=71) received isopropyl alcohol. The mean time of cord separation for infants in Group 2 (alcohol) was 10.7 days (SD 3.3), which was significantly shorter than the mean of 15.7 days (SD 3.6) in Group 1. One factor that has to be taken into consideration is that all the babies were bathed in Phisoderm every day. The authors noted that Phisoderm may not help the drying process.

Mugford, Somichiwong and Waterhouse (1986) assessed the implications of the workload for community midwives if umbilical cord care was changed. The findings are difficult to interpret since midwives often used extra treatments when babies were assigned to treatment groups. The authors point out that they wanted to study what actually happened, and so the results are pertinent. A factorial design (n=781) was used to assess 3 different powders, 3 different cleaning methods, and 2 different frequencies. The cord separation times ranged from 6.29 days (SD 1.73) to 7.14 days (SD 2.09). The authors reported that the use of Sterzac powder was associated with 0.61 extra home visits and this increased costs.

Oudesluys-Murphy, de Groot, and Eilers (1986) wrote a letter to the editor describing use of a daily bath and clean binder as the method of choice for cord care in Holland. The average time to cord separation was 6.2 days in a retrospective study of 279 healthy, term newborns.

Salariya and Kowbus (1988) assigned 400 infants to 4 different treatment regimes. Group 1 had no treatment, Group 2 was cleaned with Sterets and then dusted with Sterzac

powder, Group 3 was cleaned with Sterets only, and Group 4 was dusted with Sterzac powder only. Group 4 (Sterzac powder only) had the shortest mean time in days to separation (6.6 days). The longest mean time was Group Two (Steret only) with a time of 7.9 days. The authors concluded that minimal or no handling of the umbilical cord appears to promote faster separation. Dusting with powder was seen as minimal handling as compared to swabbing with alcohol.

Gladstone, Clapper, Thorp, and Wright (1988) conducted a randomized study of six umbilical cord care regimes with 271 infants. Antimicrobial control was equal in all treatment groups. Dry cord care was not used as a group as it was considered unsafe! Daily applications of triple dye was liked least by nursing staff and parents alike; povidone-iodine was associated with the shortest time to cord separation and consequently was preferred and recommended by the authors.

Naor, Merlob, Litwin, and Wielunsky (1989) studied cord separation in 394 infants. The two treatment groups had similar cord separation times of 6.36 (SD 2.64). One group was treated with alcohol swabs, the other with bacitracin spray (Rikospray®). The authors noted that the cords of the group treated with alcohol had an unpleasant odour. Ten percent of the babies in each group had umbilical granuloma, 59 percent of cords separated within 6 days and 100 percent separated by 20 days. The authors recommend the continued use of non-systemic local antibiotics. It should be noted that this study was funded, in part, by the makers of Rikospray®, 3M Health Care England Promedico.

Meberg and Schøyen (1990) randomized a cohort of newborn infants born within a 16 month period in Norway. One group of infants (n=1213) was treated with Sorbact®, a hydrophobic material, and the other group (n=1228) was treated with a chlorhexidine-ethanol solution. There was no difference in colonization of skin bacteria between groups. Two hundred and sixteen infants in the Sorbact® group and 194 in the chlorhexidine group grew significant organisms and there was a 7 percent infection rate. Mean time to cord separation occurred later in the Sorbact® group (6.2 days, SD 2.2) than in the chlorhexidine group (5.8 days, SD 2.1). In a previous study (1985) bath regime using an antibacterial solution made no difference to colonization and infection rates.

Bourke (1990) conducted a non randomized trial in which she examined no treatment for cord care or treatment with alcohol swabs. Babies in the trial received treatment dependent on which postnatal ward they were admitted. The 'no treatment' group (n=55) had a mean of 6.4 days to cord separation. The alcohol group (n=48) had a mean of 8.04 days. The author states that the treatment group reported less moist cords. Mothers' had been asked to rate the cord condition area on a subjective scale ranging from clean and dry to skin red and inflammed.

Mansell (1990) concentrated on the effect of the community workload when considering a change in the cord care regime in Melbourne, Australia. The comparative study was a three phase project with a small number of babies. Phase 1 (n=42) phase 2 (n=59) and phase 3 (n=19). Methylated spirits and chlorhexidine solution were compared. The conclusions are based on reported cases where cords treated with methylated spirits separated from the umbilicus in less time. Mansell also noted that the time of year affects

the length of time to cord separation. These findings are not reported anywhere else in the literature, and perhaps in a larger study these findings would not be replicated.

Watkinson and Dyas (1992) conducted a prospective study using two different cord care regimes for infants born by Caesarian Section. Group 1 (n=53) had Mediswabs® and Sterzac® powder applied to the cords. Group 2 (n=49) had water or no treatment. Forty six percent of cords for Group 2 had separated by Day 7; 26.4 percent of cords in Group 1 separated by Day 7. The authors state that while the cord separates faster with no treatment, the colonisation rates were significantly higher and therefore the savings by not treating the umbilical area have to be balanced against the expense of antibiotics that may be needed to treat infections. Limiting colonization is seen as a useful and proactive method of preventing infection. The authors criticize other British studies because they did not include colonization studies (Lawrence, 1982; Salariya and Kowbus, 1988; and Mugford et al. 1986).

Verber and Pagan (1993) compared the effectiveness of hexachlorophane powder and chlorhexidine solutions as antibacterials in reducing colonization. Although the research study also had a non treatment group, the report concentrated on the powder and solution groups. Chlorhexidine solution was associated with a noticeable delay in cord separation and therefore a heavier workload for the community midwives. The research using the solution was discontinued for this reason. The authors report concentrates on staphylococcal phage types found on umbilical cord swabs and the cord separation results are given as a percentage of cords still attached at 10 days. In the no treatment group (n=323); 7.1 percent remained attached; in the chlorhexidine solution group (n=104); 27.9

percent remained attached; and the hexachlorophane powder group (n=133), 3 percent of cords remained attached. The premise of this study appears to support the study by Watkinson and Dyas (1992), in that some sort of treatment should be continued because of the risk of infection to babies from the umbilical area. There was a delay of more than 10 days in cord separation in the no treatment group (7.1%) compared to the hexachlorophane group (3.7%). The results were reported as percentages because of the unequal numbers in each group.

Ronchera-Oms, Hernández, and Jimémez (1994) reported in a letter to the editor that using antiseptic solutions and powders prolongs the time to cord separation, but also recommended that the practice be continued. They recommended that more research be carried out to find ways to shorten the time to cord separation. They suggested that dry cord care is not acceptable because of the risk of infection.

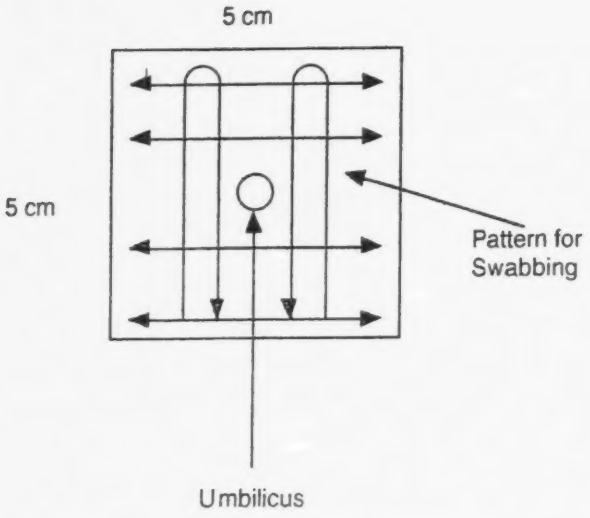
Barclay, Harrington, Conroy, Royal, and Laforgia (1994) concluded that treating cords with chlorhexidine in alcohol (n=466), delayed separation by 1.7 days (SD 0.36) when compared to no treatment (n=424). Colonisation swabs were taken at the same time and the authors reported that infants in the treatment group (n=97) and in the non treatment group (n=113) colonised with normal skin flora, although this was delayed in the treatment group. The authors reported that 4 babies had to be treated with antibiotics for suspected cord infections. They conclude that observation alone is still a safe method of care. Therefore treatment should only be started when there is inflammation or evidence of infection.

Conclusion

Umbilical cord care and cord separation times vary around the world. The reason for using antimicrobial agents is to reduce the colonization of bacteria which are assumed to be required to aid umbilical cord separation. Outbreaks of neonatal infections in nurseries persuaded physicians that infants skin should be kept free of bacterial colonisation while the infants remained in hospitals. Omphalitis is a rare event, necrotizing fasciitis even rarer. The use of antimicrobial agents is not without risk: alcohol has been associated with chemical burns and intoxication, iodine solutions with raised TSH levels, and hexachlorophane has been measured in neonatal blood samples. Research studies that measure cord separation times have not included colonization studies and have been criticized. Studies that examined colonization patterns have not been concerned with cord separation times. A remaining puzzle in the literature is the relationship between geographic area and cord separation times. North American studies reveal longer times to cord separation when compared with similar studies in other countries. In view of shorter periods of time spent in hospital following birth, nurses and midwives question the practice of antimicrobial use in umbilical cord care. Physicians continue to advocate an antimicrobial even if the treatment causes a delay in cord separation. There is no reported Canadian study of umbilical cord separation times, and American studies predate the short hospital stays postpartum that are now considered normal.

Appendix B

Umbilical Swabbing Technique



5 cm x 5 cm sterile template. Sterile cotton-tipped swab. Swab in directions shown. Place swab in sterile TSB and transport to laboratory for culture.

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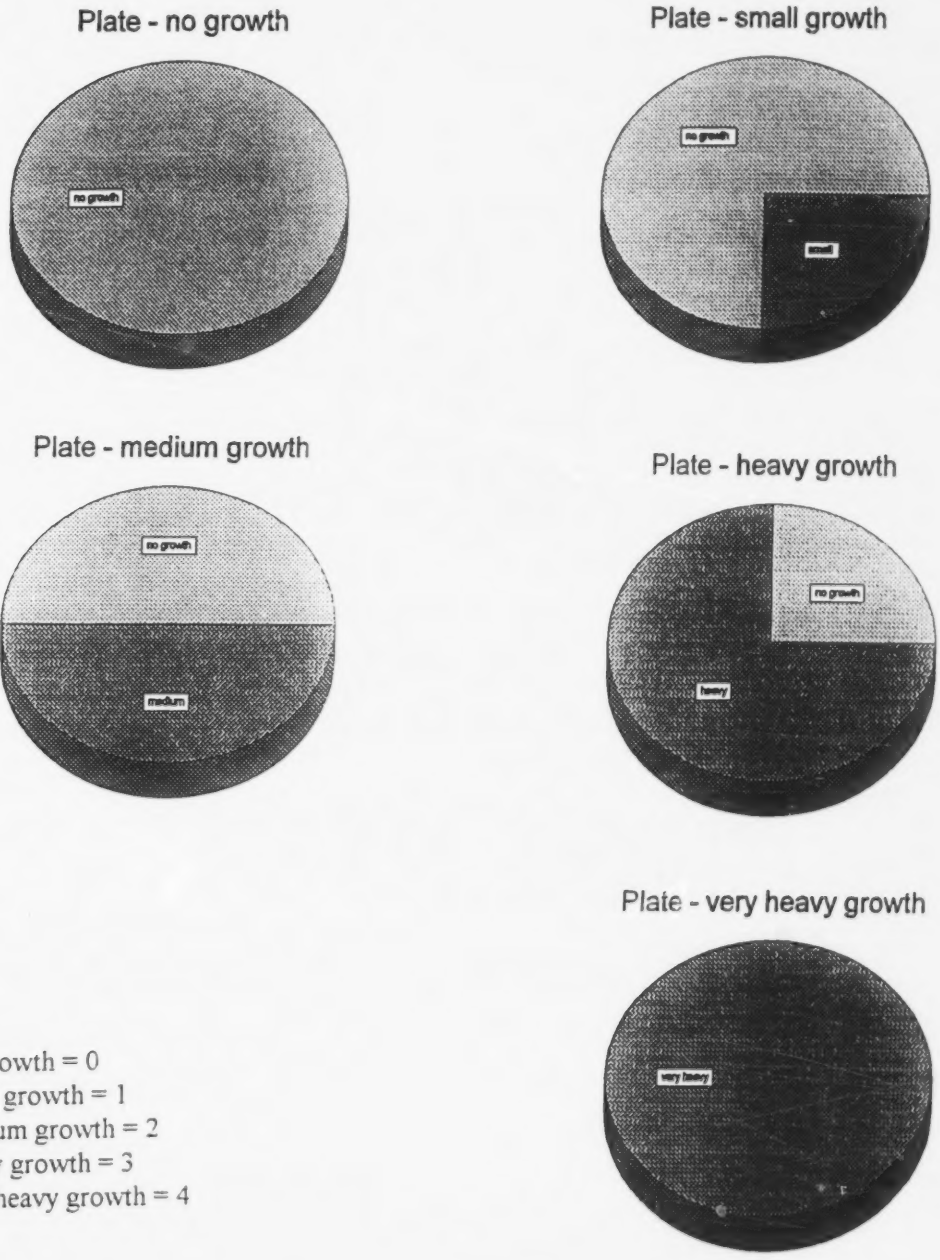
Figure 4 - Quantitative analysis of microbiology plates



no growth = 0
small growth = 1
medium growth = 2
heavy growth = 3
very heavy growth = 4

Appendix C

Clinical Trial Methodology Concerns

In order to ensure that the staff at the tertiary care hospital were informed of the upcoming study several approaches were attempted. In-service presentations appeared to be the most appropriate method of informing case room staff, but in-services did not reach a large number of staff. Approximately 150 staff members could have been affected by the study and a large number work part time and casual. Although In-services were the intended method of dissemination of information, e-mail to all staff proved to be the most effective. The 70 physicians who have admitting privileges to the obstetrical unit were sent a letter outlining the study. Physicians and nursing staff who were interested in the study were invited to discuss any issues with the investigator on a one-to-one basis.

The nursing staff had more difficulty with the study for several reasons. Firstly, the nursing staff had been through a major reorganisation of health care services in the region, including the closing of the other large tertiary care maternity unit in the region. The reorganisation caused an increase in workload as well as acuity. The investigator and assistant needed to be acutely sensitive to the tremendous pressure that the staff worked under on a day to day basis. Secondly, the hospital has not traditionally been involved with nursing research. The Unit Managers and Clinical Nurse Specialists, while fully supporting the study, were unable to insist that the staff co-operate with the study. The nursing staff only co-operated with the study if the researcher or research assistant sat on the unit. While a few nurses actually discouraged new parents from participating, the tactics were generally more those of passive resistance.

The study had been designed to ensure that no extra work was required of the nursing staff. The ward clerks placed an information sheet in each admission package; the nurse who admitted the prospective parents' was asked to give them the information sheet. If the parents wished to participate or had questions, the nurse was asked to page the researcher. Many of the nurses were unwilling to page the researchers or allow them access to the parents. The situation was better when the researcher was present in the case room, however access to potential participants for answering questions, randomising, and discussing issues was difficult.

In order to facilitate cooperation from the nursing staff the researcher often worked as a volunteer, and performed tasks such as moving patients from room to room; room to operating room; admitting patients; and on several occasions acting as a coach for labouring women. The researcher was often greeted with the cheerful news that the nurses had forgotten to page them, and they were sorry! At the time this was extremely frustrating! In retrospect it is hardly surprising considering the acuity of the prospective mothers who are cared for and the turnover of clientele. The average mother, primigravida or multigravida, would remain in hospital for one night post delivery. Of the study participants who were delivered by lower segment caesarian section (n=10) three were discharged before day three. One Unit Manager, who has a midwifery and post graduate nursing background, was particularly encouraging and stated that this particular piece of research was ground breaking in terms of setting a welcome precedent for the Unit.

In summary, many approaches were used to ensure that all new parents were given the opportunity to participate in the study. However, passive resistance is very difficult to overcome. An understanding of the politics of a unit is very important to elucidate, and it can be very difficult to become accepted in a unit without being seen to side with one faction or another.

Demographic Data Analysis

There was a significant difference in the number of boys and girls in group one as compared to group two. The higher incidence of multigravida was expected as families having second or subsequent babies know how to clean the cord and were more open to changing to a different regime. It is surprising that so many primigravid women were keen to participate. The primigravid women certainly asked more questions and rang the researcher for advice and extra home visits.

Table 6 - Demographic Data Comparison

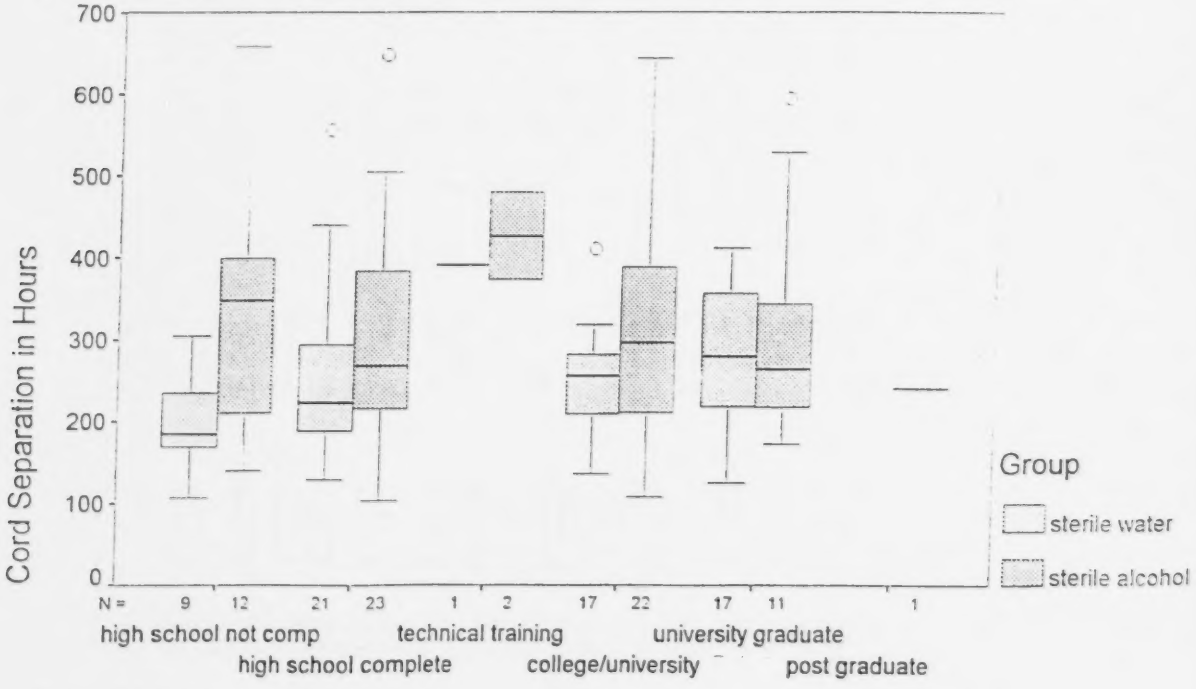
Demographic / Group	Group One		Group Two	
Gender	Boy	39 (60%)	Boy	34 (48%)
	Girl	26 (40%)	Girl	37 (52%)
Diaper Use	Disposable	49 (75%)	Disposable	58 (82%)
	Cloth	16 (25%)	Cloth	13 (18%)
Delivery Type	SVD	59 (91%)	SVD	69 (97%)
	LSCS	6 (9%)	LSCS	2 (3%)
Maternal Parity	Primigravida	27 (42%)	Primigravida	30 (42%)
	Multigravida	38 (58%)	Multigravida	41 (58%)
Maternal Age	less than 20	4 (6%)	less than 20	3 (4%)
	20-30	33 (51%)	20-30	34 (48%)
	30-40	28 (43%)	30-40	34 (48%)
Maternal Education	less than grade 12	8 (11%)	less than grade 12	12 (17%)
	highschool completed	22 (38%)	highschool completed	23 (32%)
	technical college	1 (1%)	technical college	2 (2%)
	college or university	17 (25%)	college or university	21 (30%)
	graduate education	17 (25%)	graduate education	13 (19%)

Maternal Education

The education levels of the mothers is interesting. While the levels are equal across the groups, the level of education above some years of college is particularly high. In the metropolitan area there is a very large university and several colleges offering courses that can be granted towards an undergraduate degree. The metropolitan area as a whole has a high percentage of adults with post secondary education around 40% (personal communication, S. Stamhuis, 20 March 1996). Fifty percent of the mothers in group 1 had some university or college education, and 49% in group 2. These figures

reflect the normal findings that those with higher education are more willing to participate in studies. It had been hoped to direct the study at a level that all women would understand the consent form and information sheet (assessed at grade 8 and grade 6 levels respectively). Of the women who withdrew their infants from the study (n=12) three were First Nations, one was a new immigrant, and the others were caucasian and born in Canada.

Figure 5 - Cord separation by maternal education and group



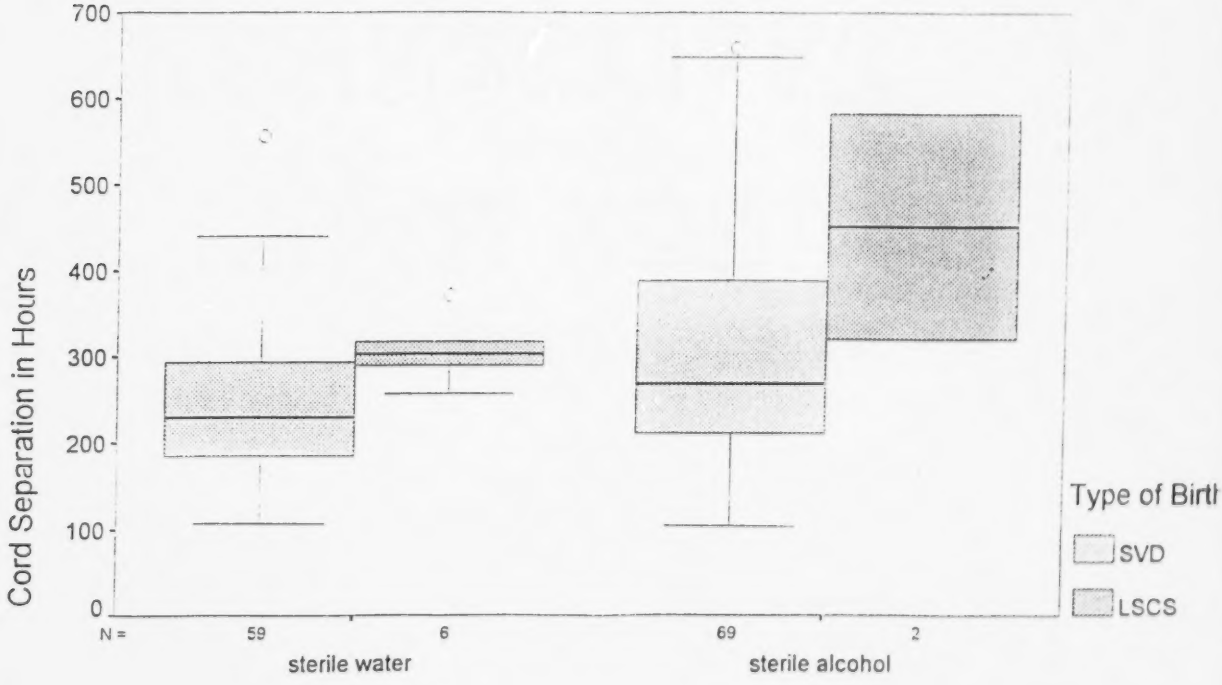
Type of delivery

Enrolling subjects who had been delivered by LSCS proved awkward. Women who were to have elective LSCS were seen in a preadmission clinic, the women were all given information sheets. The researchers attended each preadmission clinic to distribute information sheets and answer questions if the clinic nurse could not do so. Problems

arose if the mother was not seen on the day of delivery prior to surgery. While most women had regional analgesia some sedation was also given and informed consent under these conditions are not possible. New fathers were asked to give consent but many would not give permission without their partners consent!

The researchers learned many ways of overcoming these problems and perhaps if the study had continued they would have been more successful in recruiting. Of interest, the month of June 1996 was busier than usual. There were 456 total live births with a 20.6% LSCS rate. The LSCS rate was higher than usual, with 13 LSCS in one 24 hour period. The numbers of subjects recruited into the study delivered by LSCS is too small to draw any meaningful conclusions. Figure 6 is presented out of interest alone.

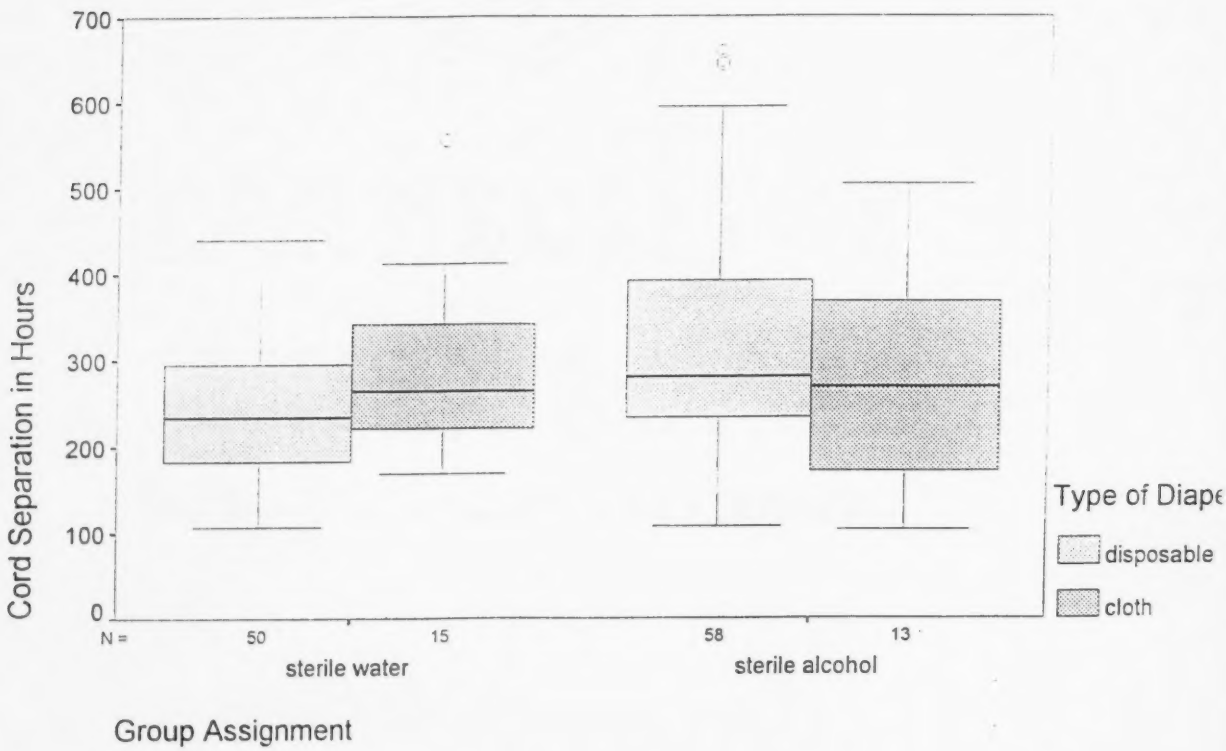
Figure 6 - Cord separation by delivery and group



Diaper use after discharge from hospital

While the infant's were in hospital they were all nursed in cloth diapers. Data was collected following discharge to ascertain whether they wore cloth or disposable diapers. If the parents indicated that disposable diapers had been used at all then the infant was placed in the disposable diaper group. The findings are presented and between group difference or colonization could not be calculated because all the babies wore cloth diapers in hospital. In length to separation the group difference was f .023 and p .881.

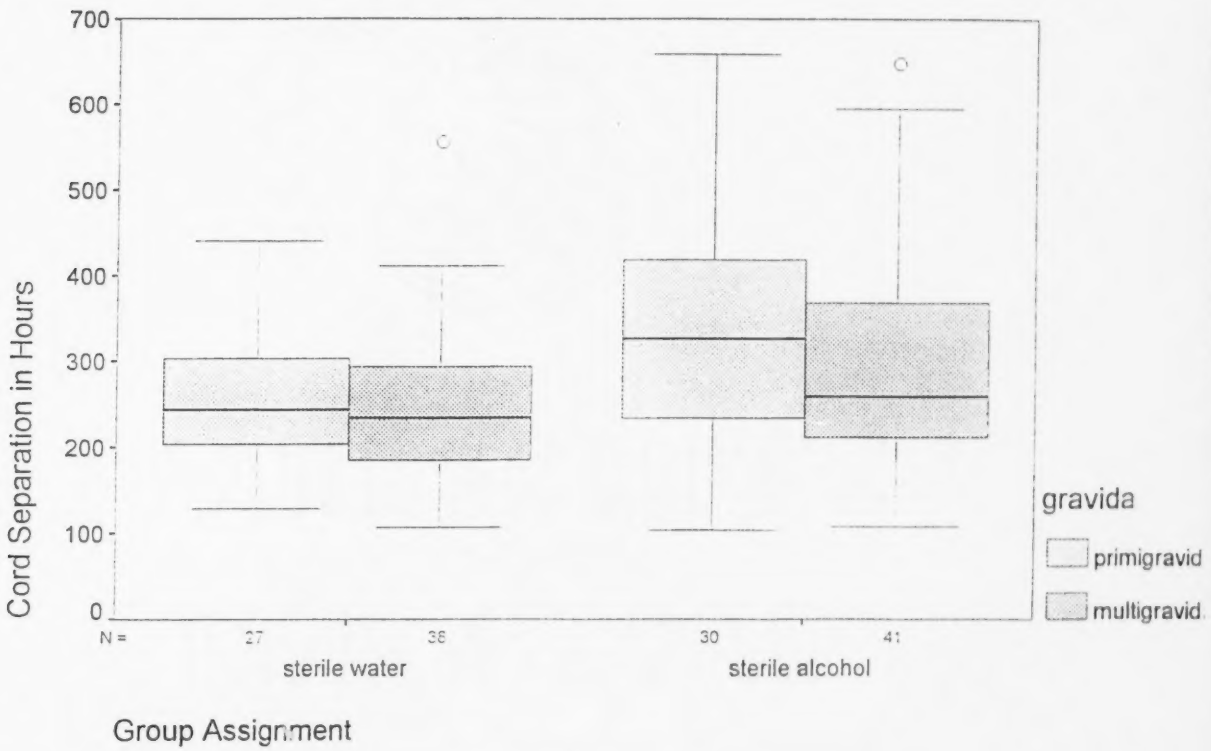
Figure 7 - Cord separation by diaper use and group



Maternal Parity

Maternal parity was designated as group one (mother's first baby), and group two (second or subsequent baby). Parity did not affect the time of cord separation (f = .556, p = .457) or colonization of umbilical cord swabs (f = 1.546, p = .216).

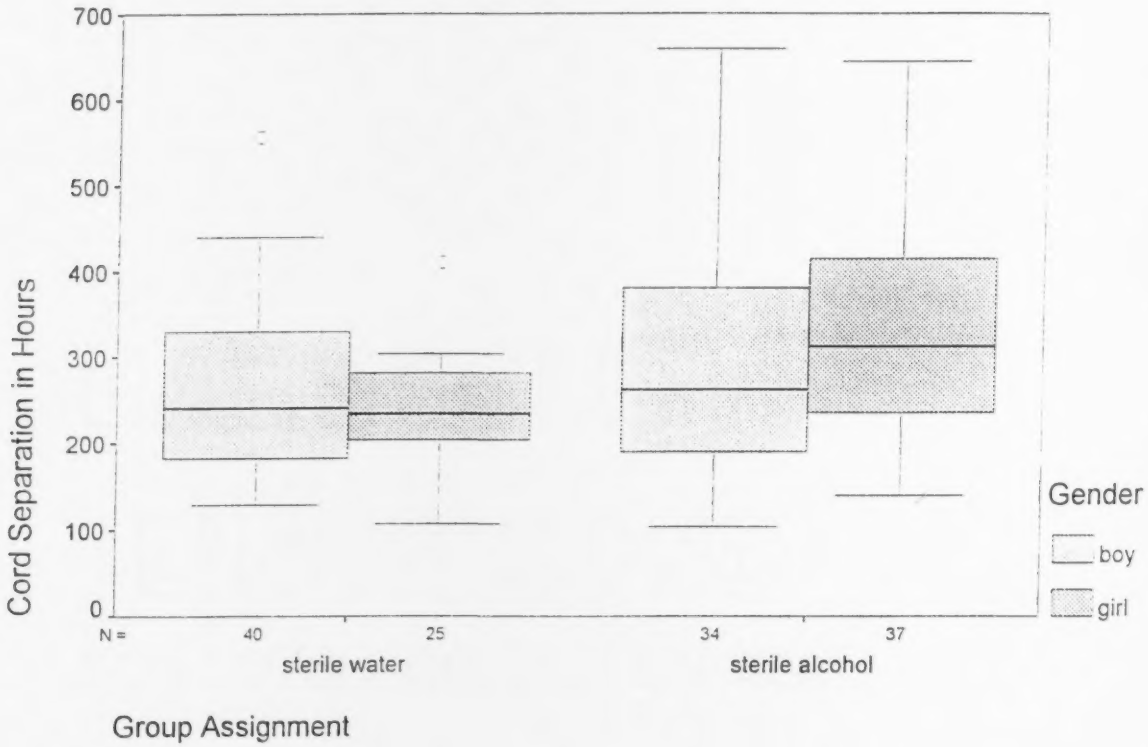
Figure 8 - Cord separation by parity and group



Gender differences in the two groups

The group treated with sterile water had 60% boys and 40% girls. Group two had 48% boys and 52% girls. This demographic anomaly upset the statistical analysis, as there were only 25 girls in group one. In the cord separation analysis and colonization studies there was no significant difference.

Figure 9 - Cord separation by gender and group



Attrition and Methodology Problems

The problem of attrition was considered in the study design. By making a home visit within 48 hours of discharge from hospital it was hoped that the parents would be more receptive to contacting the researchers when the cord separated. No one refused a three day visit; one mother requested a day four visit as she had so many out of town visitors, one mother had her house recarpeted on day three and requested a later day. The reasons for dropping out of the study are given in appendix J. If the parents had not contacted the researchers by day 10, a phone call or visit was made to discover the state of the umbilical cord and to deliver more cleaning swabs as required. Parents who telephoned for advice or who requested an extra visit were all phoned or seen within two hours of the initial contact. These visits took priority over the scheduled three day or separation day visits.

There were some problems with the final visits. Many families (n=34) did not let the researchers know that the cord had separated, although they were all apologetic in retrospect. The reasons for not informing the researcher were:

1) on holiday out of the city,

2) language barriers,

3) reluctance to use the paging system,

4) moving to a different address,

5) no access to a telephone, and

6) simply forgetting. July is not a good month for a clinical trial because of summer vacations. Subjects could not page us with a rotary telephone. Careful

assessment of the address and the chance of spending time at a relatives house, usually a mother, must be ascertained prior to discharge from hospital. Language barriers will always be problematic. It is important to be as inclusive as possible in any study and to exclude English-as-a-second language families is not acceptable in our multicultural society. The English-as-a-second-language subjects were targeted for a visit on day 10 because it was our experience that they did not answer the telephone or have answering machines. The families without phones were visited on day 7 and 10 to ascertain the state of the umbilical cord.

Case histories of subjects who dropped from the study

There were twelve dropouts from the study. One subject was accidently enrolled, the number allocated and the envelope opened when it was discovered that the family lived one hour and forty minutes from the city and not on a city street address with the same name. One subject was seen by the research team one day and the cord was dry and healing; the following day the infant was taken to a family physician who deemed the cord to be malodorous and requested that the family use hydrogen peroxide - the cord dried and separated the following day. This family did not inform the researchers until five days later.

Table 7 - Reason for attrition from the study

Reason for dropout from study	**Number**
Infant admitted to NICU	1
Parents out of town	2
Water swabs made "baby scream"	1
Water swabs kept the cord "too moist"	1
Family lived out of metropolitan area	1
Family physician or health professional advised cord care with alcohol	4
Family physician advised cord care with hydrogen peroxide	1
Cord remained attached longer than six weeks, stopped using alcohol.	1

Group B Streptococcal colonisation - maternal and pediatric

The incidence of GBS colonization varies between ethnic groups and geographic locations. The incidence is between 7-10% in Canada; the incidence at the study hospital has reached as high as 40% (personal communication, S. Chandler, 10 May 1996). Group B streptococci infections are a significant cause of maternal and neonatal morbidity (Katz, 1993). The treatment of Group B streptococci (GBS) positive high risk women in labour is beyond question. High risk women are those in premature labour, prolonged labour of over 18 hours, temperature in labour >37.5°C, diabetes, multiple gestation, polyhydramnios, previous infant affected by GBS disease, and heavy maternal colonization. Neonatal group B streptococcal infections manifest in two thirds of cases within 24 hours of delivery, the remaining third after 7 days of life, usually as meningitis (Burman et al., 1992). As higher than expected GBS positive women have been found in the population of women delivering in the study hospital a particularly vigorous attempt is made to reduce the incidence of GBS infected infants. Chlorhexidine in solution has been used to irrigate the vagina in labour to eliminate the organism with mixed results (Burman et al, 1992; Lindeman, Henrichsen, Svenningesen, and Hjelle, 1992). Chlorhexidine as a lubricant on gloves used in vaginal examinations also produced equivocal results (Henrichsen, Lindeman, Svenningesen, and Hjelle, 1994; Hennequin, Tecco, and Vokar, 1995). GBS can be successfully treated by intravenous antibiotics in labour. GBS is sensitive to penicillins, cephalosporins, and clindamycin (Katz, 1993). A choice of antibiotics is therefore available to help reduce the incidence of a devastating disease which has a high mortality especially among preterm infants. Penicillins can be

found in therapeutic levels in cord blood one hour after maternal infusion (Morales, Lim, Walsh, 1986). Early onset GBS is the disease that can be minimised by treating GBS positive women in labour (Boyer and Gotoff, 1988).

Pregnant women are routinely screened for group B streptococci by means of anorectal swabs obtained in the third trimester at the study hospital. The accepted practice at the hospital is particularly aggressive (personal communication, Dr. G. Black, 1 July 1996). Most physicians prescribe antibiotics intravenously every four hours throughout labour for all women who are GBS positive as well as GBS unknown. The most usual antibiotic administered is Ampicillin 2 grams every four hours.

In the umbilical cord care study the incidence of GBS positive anorectal swabs (taken between 32 and 36 weeks gestation) was 24 (16.2%). This is well below the expected number at the study hospital of 40%.

Table 8 - Mothers who received antibiotics in labour and incidence of GBS

Demographic/Group	**Group one**	**Group two**
Antibiotics in labour	18 (24.6%)	15 (20.2%)
No antibiotics in labour	55 (75.3%)	59 (79.8%)
GBS positive	14 (19%)	10 (13.5%)
GBS negative	51 (70%)	57 (77%)
GBS unknown	8 (11%)	7 (9.5%)

All the babies enrolled in the study were bathed in chlorhexidine gluconate within the first three hours following delivery. The incidence of GBS in our study was low 3% (5 infants - 6 samples). Two mothers were GBS negative and not given antibiotics in labour, two were GBS positive and given antibiotics in labour, the fifth women was GBS unknown and was not treated. One sample was obtained on day three and again on the day of cord separation by the research assistant (mother GBS negative). The colonization was classified as medium growth on both specimens. The remaining four samples were obtained on the day the cord separated and were collected by the investigator. This can be explained in that the research assistant tended to make the three day visits and the investigator visited on the day of separation. One specimen was classified as small growth (mother GBS positive). The specimen of the untreated mother who was GBS negative showed heavy growth. The remaining specimens were very heavy growth (one GBS negative and one GBS positive mother). All these specimens were collected within 24 hours of cord separation. All the infants were well at the time of cord separation and no subsequent infections have been reported to the investigator.

The issue of GBS re-colonization has been investigated. In studies where women and their partners were treated with oral antibiotics between 32 and 36 weeks gestation, GBS status remained unchanged (Gardner, Yow, Leeds, Thompson, Mason, and Clark, 1979). The results of this study are reported out of interest as GBS colonization in well infants, as early as three days in one case, was unexpected especially as the infants were all bathed in chlorhexidine. The GBS colonization caused most anxiety to the microbiology technologist; the researcher was unaware until the completion of the study. A mild soap

is normally recommended as suitable for bathing newborns, Hibitaine is probably too strong a solution and may cause rashes (American Academy of Pediatrics, 1974). Further study is required to describe the incidence of colonization of GBS of newborn infants, with maternal GBS status, maternal antibiotics and cleaning solutions as the variables.

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Appendix D
Information Sheets and Consent Forms

Umbilical Cord Care: Effects of Care with Water Alone or Alcohol on Cord Separation Time

I am interested in the best way to clean your baby's umbilical cord (belly button) area. The umbilical cord is the cord that attached your baby to the placenta when you were pregnant. Once the baby is born, the cord drys up and falls off because it is not needed anymore.

Everyone who is the study will be put in one of two groups. You will not know which group you are in until after you decide to be in the study. We will not know either. You will have an equal chance of being in either group. This is called random assignment. In other words, this will be done in a fair way as in pulling numbers from a hat.

One group will be asked to use sterile water to clean the baby's cord. If you are in this group, you will be given packages of sterilized water. You will be asked to clean the cord area with a sterile water swab four times a day until the cord falls off.

One group will be asked to use alcohol to clean the baby's cord. If you are in this group, you will be given little packages of alcohol. You will be asked to clean the cord area with a fresh package four times a day until the cord falls off.

If you are in either group, we will take a swab of the cord area about 3 hours after your baby is born. This is so that we can see if there are any germs in this area. This should not upset your baby. We will come to your home and do this again when your baby is three days old and on the day that the cord falls off. If you are still in the hospital on either of these days, we will visit you here. Please leave a message for us at 477-4639 when you notice that the cord has fallen off. We will call you after 10 days if we have not heard from you by then.

If you think that your baby has an infection in the area of his cord, taking part in this study will not replace the care that you get from your doctor.

If you wish to take part in the study, please fill out the consent form. If you have any questions about the study, please contact us at any time.

Researcher

Jennifer Medves, RN, MN Candidate

Supervisor
Beverley O'Brien, RN, DNSc
Associate Professor, Faculty of Nursing
University of Alberta
University 492-8232 or Royal Alexandra
Hospital 477-4639

Feuille D'information

Les Soins du Cordon Ombilical: Les Effects des Soins avec L'eau Seulement ou avec L'alcool sur le Temps de Séparation du Cordon Ombilical

Je m'intéresse à la meilleure méthode possible pour nettoyer le cordon onbilical de votre bébé (le nonbrif). Le cordon ombilical est le cordon qui relie votre bébé au placenta durant la grossesse. Lorsque l'enfant vient au monde le cordon sèche et tombe à cause qu'il n'est pas nécessaire.

Tous ceux qui prendront part à l'étude seront placés dans deux groupes différents. Vous apprendrez dans quel groupe vous serez seulement après avoir joint l'expérience. Nous ne saurons pas autrement. Vous aurez des chances égales d'être dans l'un ou l'autre de ces groupes. Ceci s'appelle désigné au hasard. En d'autres mots, ceci sera fait d'une manière juste comme des numéros tirés d'un chapeau.

Un groupe devra utiliser de l'eau afin de nettoyer le cordon. Si vous êtes dans ce groupe on vous donnera un paquet d'échantillons d'eau stérilisé. On vous demandera de nettoyer la région du cordon à l'aide de l'eau stérilisé quatre fois chaque jour jusqu'à ce que le cordon tombe.

Un groupe devra utiliser de l'alcool afin de nettoyer le cordon. Si vous êtes dans ce groupe on vous donnera un paquet d'échantillons d'alcool. On vous demandera de nettoyer la région du cordon à l'aide d'alcool quatre fois chaque jour, jusqu'à ce que le cordon tombe.

Si vous êtes dans un des deux groupes nous allons prendre un prélèvement dans le région du cordon environ trois heures après la naissance de votre enfant. De cette façon nous pouvons déterminer s'il y a des germes dans cette région. Ceci ne devrait pas affecter votre bébé. Nous allons nous rendre chez vous trois jours après la naissance pour faire à nouveau un prélèvement et aussi lorsque le cordon tombera. Si vous êtes toujours à l'hôpital lors d'une de ces journées nous irons vous rendre visite. S'il-vous-plait de laisser un message pour nous au numéro 477-4639 lorsque vous remarquerez que le cordon a tombé. Nous allons vous appelez après dix jours si nous n'avons pas eu de vos nouvelles.

Si vous penser que votre bébé souffre d'une infection dans la région du cordon ombilical, le fait de prendre partie à cette étude ne remplacera pas les soins que vous recevez de votre médecin. Si vous désirez prendre part à cette étude, s'il vous plaît compléter le formulaire de consentement. Si vous avez des questions concernant l'étude, vous êtes prier de nous contracter n'importe quand.

Responsables de la recherche
Jennifer Medves, RN, MN Candidate

Superviseur
Beverly O'Brien RN, DNSc
Faculty of Nursing, University of Alberta or
Royal Alexandra Hospital 477-4639

Cuidado del Cordón Umbilical: Efectos del Cuidado con Agua Solamente o Con Alcohol en el Tiempo de Separación Del Cordón

Yo estoy interesada en la mejor manera de limpiar el area del cordón umbilical de su bebé (ombligo). El cordón umbilical es el cordón que une a su bebé a la placenta cuando usted esta embarazada. Una vez el bebé nace, el cordón se seca y se cae porque ya no se necesita más.

Cada madre que esta y bebé siendo estudiads debrá ser puesta en uno de dos grupos. Usted no sabrá en que grupo estará hasta que usted decida tomar parte en el estudio. Nosotros tampoco lo sabremos. Usted tendrá una oportunidad de estar en cualquier grupo. A esto se le llama asignación al azar. En otras palabras, esto será hecho en una manera justa como cuando se sortean números de un sombrero.

A un grupo se le pedirá que use agua esterelizada para limpiar el cordóndel bebé. Si usted esta en este grupo, se le darán paquetitos de agua esterelizada. Se le pedirá que limpie el area del cordón con un paquete fresco quatro veces durante el dia con un cambio de pañal.

A un grupo se le pedirá que use alcohol para limpiar el cordón del bebé. Si usted está en este grupo, se le darán paquetitos de alcohol. Se le pedirá que limpie el area del cordón con un paquete fresco quatro veces durante el dia con un cambio de pañal.

Si usted está en cualquiera de los grupos, nosotros tomaremos una muestra con un algodón del area del cordón 3 horas después que su bebé nació. Esto es para ver si hay gérmenes en esta area. Esto no debería perturbar a su bebé. Nosotros vendremos a su hogar y haremos lo mismo otra vez después que el bebé tiene tres días, de nacido y en el día que el cordón se cae. Si usted esta todavía en el hospital en cualquiera de estos días, nosotros la visitaremos allí. Por favor dejenos un mensaje al 477-4639 cuando usted note que se ha caído el cordón. Nostros la llamaremos después de 10 días si para entonces no hemos oído nada de usted.

Si usted piensa que su bebé tiene una infección el area de su cordón, el tomar parte en este estudio no reemplazará el cuidado que usted obtiene de su doctor.

Si usted desea tomar parte en este estudio, por favor llene el formulario de consentimiento. Si usted tiene algunas preguntas acerca del estudio, por favor comuniquese con nosotros a cualquier hora.

Investigador

Jennifer Medves, RN MN Candidate

Supervisora

Beverly O'Brien, RN, DNSc
Associate Profeesor, Faculty of Nursing
University of Alberta
University 492-8232 or Royal Alexandra Hospital 477-4639

臍帶護理：

清水或酒精對臍帶脫落的影響

我對研究最佳清潔嬰兒臍帶區的方法感到興趣。臍帶是當你懷孕時嬰兒連結著胎盤的那條帶，一旦嬰兒出生，這帶就會失去它的作用而干枯脫落。

參加這一研究的嬰兒共分兩組，只有當你決定參加這一研究時，你才知道自己編在何組。即使我們事前也不知道你屬於那一組，這種方法叫做隨機抽樣，有如把寫好了的號碼放在帽子裏抽簽一樣。

其中一組是用經過滅菌處理的清水清潔嬰兒臍帶區，如你屬這一組，你將會獲得一些以小瓶包裝的無菌清水，當你每次替嬰兒換（尿布）時，你要用一瓶新鮮的無菌清水去清潔嬰兒的臍帶區。

另一組是用酒精清潔嬰兒的臍帶區。如你屬這一組，你將會得到一些以小瓶包裝的酒精，在你換（尿布）時，要啓用一瓶新鮮的酒精清潔臍帶區，直至臍帶脫落爲止。

不管那一組，在嬰兒出生後三小時，我們將會用棉花棒在嬰兒臍帶區輕抹皮膚，取樣，以便檢驗該區是否有微生物存在。這種取樣不會令嬰兒不快，我們將會在嬰兒出生後第三日以及在臍帶脫落那天會再做同樣的取樣檢驗。如果在取樣的日子，你還在醫院，我們會在醫院替你取樣。當你發現臍帶脫落時，請即打電話 477-4369 留言通知我們。如果在十日內我們還收不到你的消息，我們將會打電話跟你聯絡。

如果你願意參加這項研究，請填具一份"同意書"。如對這項研究有任何疑問，請隨時聯絡我們。

研究員：Jennifer 註冊護士.碩士生
研究導師：Beverley O'Brien 註冊護士.護士學博士
亞省大學 492-8232 或 Royal Alexandra Hospital 477-4639

CONSENT FORM

RESEARCH TITLE: A comparison of water and alcohol in promoting healing of the umbilicus and reducing the length of time to separation of the umbilical cord.

INVESTIGATOR: Jennifer Medves, RN, BN
Faculty of Nursing
University of Alberta

SUPERVISOR: Dr. B. O'Brien, PhD
Associate Professor,
Faculty of Nursing
University of Alberta
Telephone: 492-8232

PURPOSE: I want to measure the time in days that it takes for your baby's umbilical cord to separate. I want to discover if the solution that we normally clean the cord with allows the cord to separate quickly.

PROCEDURE: Your baby will be assigned to either the water group or the alcohol group if you agree to take part. The researcher will show you how to clean the cord. You should clean the cord four times a day until the cord separates. A swab will be taken on the day your baby is born and again on the third day. You will be discharged home from hospital on the day your doctor decides and the researcher will visit you at home. On the day that the cord separates you will be asked to telephone me and I will come to your home and take a final swab. The baby's hospital record will be looked at by the researcher to get information about the baby's birth.

There will be no harm to your baby if you participate in this study. Your baby may not directly benefit from this study. Results from this study may help nurses decide which is the best of way cleaning the cord to promote earlier separation. You do not have to be in this study if you do not wish to be. If you decide to be in this study, you may drop out just by telling me. Taking part in this study or dropping out will not effect your care that you get.

Your name or your baby's name will not appear in any publication or discussion about this study. A code number will appear on any forms or swabs. The list of your names will be kept in a locked file. Only the researcher will have a record of who was in the study. If the information from the study is looked at in future years, the researcher will get permission from a university ethical review committee.

CONSENT: I understand the above study. Any questions that I had have been answered. I know that I can contact you whenever if I have questions. I have been assured that my name will not be revealed and the records will be kept confidential. I know that I am free to drop out of this study at any time and that it will not affect the care that I get. I will be given a copy of this consent form to keep. Taking part in this study will not replace the care that I get from my doctor.

(signature of parent of infant and date)

(signature of Researcher and date)

FORMULE DE CONSENTEMENT

TITRE DE LA RECHERCHE: Comparaison de l'eau et l'alcool dans le processus de guérison du cordon ombilical et la réduction du temps requis pour la séparation de celui-ci.

ENQÛETEUR: Jennifer Medves, RN, BN
Faculty of Nursing
University of Alberta

SUPERVISEUR: Dr. B. O'Brien, RN, DNSc
Faculty of Nursing
University of Alberta

L'OBJECTIF: Je veux déterminer le nombre de jours qui est necéssaire pour que le cordon ombilical se sépare de votre bébé. J'aimerais découvrir si la solution que l'on utilise pour nettoyer le cordon permet à celui-ci de se séparer plus rapidment.

MARCHE À SUIVRE: Votre bébé fera partie du groupe d'eau, ou celui de l'alcool, si vous voulez prendre part. Les responsables de la recherche vous montrerons comment nettoyer le cordon. Vous allez devoir nettoyer celui-ci quarte fois chaque jour jusqu'à ce que le cordon se sépare. Un prélèvement à l'aide d'un tampon d'ouate sera pris le jour de la naissance du bébé et une autre fois le troisième jour. Vous aurez votre congé de l'hôpital lorsque votre médecin le décidera et les responsables de la recherche iront vous visiter à la maison. Le jour où le cordon va se séparer vous devrez m'appelé et j'irai chez vous afin de prendre un dernier prélèvement. Le dossier de l'hôpital du bébé sera reviser par les responsables de verifier sa date de naissance.

Il n'y aura aucun mal de fait à votre enfant si vous participez à cette étude. Votre bébé ne profitera pas directement de cette expérience. Les résultats de l'étude aideront les infirmières à décider de la meilleure marche à suivre en ce qui a trait au nettoyage du cordon pour une séparation plus rapide. Vous n'avez pas à faire partie de l'étude si vous ne voulez pas. Si vous décidez d'en faire partie vous pouvez vous en retirez, vous n'avez qu'à me le dire. Prendre part à l'expérience ou en sortir n'affectera pas la qualité des soins que vous recevrez.

Votre nom ou celui de votre enfant n'apparaîtra pas sur aucune publication ou discussion sur l'étude. Un code sera utiliser sur les formulaires et les prétevements. La liste des noms sera gardée sous clé. Il n'y aura que les responsables de l'étude qui auront accès aux noms des participants. Si l'information de l'étude doit être reviser dans le futur les responsables de l'experíence devront en faire la demande par le permission du comité de revision éthique.

CONSENTEMENT: Je comprends l'étude ci-haut. Toutes les questions que j'avais ont été répondues. Je sais que je peux vous contacter n'importe quand si j'ai des questions. J'ai été assuré que mon nom ne sera pas publié et que les dessiers seront tenus confidentiels. Je sais que je suis libre de me retirer de cette étude n'importe quand sans que cela n'affecte la qualité des soins que je reçois. Une copie de la formule de consentement me sera remise afin que je puisse la gardée. Prendre part à cette étude ne remplacera pas les soins que je reçois de mon médecin.

_____ _____

(signature des parents de l'enfant et la date) (signature du responsable de la recherche et la date)

FORMLARIO DE CONSENTIMIENTO

TITULO DE INVESTIGACION: Una comparación de agua y alcohol en promover sanamiento del cordón umbilical y la reducción del tiempo de la separación del cordón umbilical.

INVESTIGADORA: Jennifer Medves, RN, BN
Faculty of Nursing
University of Alberta

SUPERVISORA: Dr. B. O'Brien, RN, DNSc
Faculty of Nursing
University of Alberta

PROPOSITO: Quiero medir el tiempo se toma en días para que el cordón umbilical de su bebé se separe. Quiero descubrir si la solución que normalmente nostros usamos para limpiar el cordón permite que el cordón se separe más rápidamente.

PROCEDIMIENTO: Su bebé será al grupo de agua o al grupo de alcohol si usted esta de acuerdo en tomar parte. La investigadora le enseñará como limpiar el cordón. Usted deberá limpiar el area del cordón quatro veces durante dia con el cambio del pañal hasta que el cordón se separe. Un algodón será usado para tomar una muestra en el día que su bebé nace y de nuevo al tercer día de nacido. A usted se le enviará a su casa el día que el dotor lo decida y la investigadora la visitará a usted en su hogar. En el día que el cordón se separa se le pedirá que me llame por teléfono para tomar una muestra final. El registro hospitalario de su bebé será observado por la invesigadora para obtener información acerca nacimiento del bebé.

Ningún daño se le causará a su bebé si usted participa en este estudio. Su bebé podría no beneficiarse directamente de este estudio. Los resultados de este estudio podrían ayudar a las enfermeras para decidir cuál es la mejor forma de limpiar el cordón para fomentar su separación temprana. Usted no tiene que participar en este estudio si usted no lo desea. Si usted acepta participar en él, usted puede abandonarlo, solamente me avisa. El tomar parte en este estudio o abandonarlo no afectará usted obtiene.

Su nombre o el de su bebé no aparecerán en ninguna publicación o discusión acerca de este estudio. Un número de código aparecerá en cualquier muestra o formularios. La liste con sus nombres estarán guardados en un archivero bajo llave. Solamente la investigadora tendrá un registro de quién participó en el estudio. Si la información del estudio es vista en años futuros, la investigadora tendrá que obtener un permiso de un comite etico revisión de una universidad.

CONSENTIMIENTO: Yo entiendo del estudio arriba mencionado. Cualquier pregunta que yo haya contestado. Yo se que puedo comunicarme con usted cuando quiera que yo tenga preguntas. Me han asegurado que mi nombre no será revelado y los registros serán mantenidos confidenciales. Yo se que soy libre de abandonar este estudio a cualquier hora y que no afectará el cuidado que yo obtenga. Me será entregada para que yo guarde una copia de este formulario de consentimientio. El tomar parte en este estudio no reemplaza el cuidado que yo obtengo de mi doctor.

_____ _____

(Firma de la madre del infante y fecha) (Firma de la Investigadora y fecha)

同意書

研究課題：

比較水和酒精如何促使臍帶痊愈及縮短臍帶脫落期

鑒察員：

Jennifer Medves, RN,BN
Faculty of Nursing
University of Alberta

研究導師：

Dr. B. O'Brien,phD
Associate Professor.
Faculty of Nursing
University of Alberta
Telephone: 492-8232

研究目的：

我想測量你的嬰兒的臍帶脫落的天數，並研究在正常清潔臍帶時，洗液會否使臍帶脫落快些。

步驟：

如果你同意，你的嬰兒將會安排在清水組或酒精組。研究員會教你如何清潔臍帶區。清潔臍帶應在每次換（尿布）時進行。嬰兒在出生那天及在出生後第三日將會做一個棉花棒輕抹臍帶區的檢驗，察看是否有微生物的存在。如醫生讓你出院，我們將到府上做這檢驗。在臍帶脫落那天，請打電話給我們以便做最後一次棉花棒檢驗。研究人員爲了進一步了解情況，他們會參考嬰兒在醫院的記錄。

你參與這項研究不會給你的嬰兒帶來損害。你的嬰兒或許並未直接受益，但這項研究的結果，將會幫助護士選擇最好的方法，使臍帶早些脫落。如果你不願意繼續參加這項研究，你可隨時退出。如果你願意參加這項研究，可隨時通知我們。參加或停止參加這項研究將不會影響你的嬰兒所應獲得的護理。

你和嬰兒的名字均不會在任何刊物及討論會上被應用。你的"同意書"及取樣的棉花棒都會編定一個特定的號碼。你的名字將會被放在上了鎖的文件櫃內，只有研究人員才知道參與者的名單。將來當研究人員要參閱這些文件，必須經過大學一個叫做【倫理委員會】的批准才成。

同意書：

本人明白上述研究之內容。一切問題亦已獲得解答。本人明白如有任何問題時可以與閣下聯絡，並明白本人之姓名將不會被公開，及該項記錄將絕對保密。本人明白可隨時中止參加是項研究。在參與這項研究時，將不會影響本人及嬰兒應有的護理。此同意書之副本將由本人保存。

簽名：

Tờ Đồng Ý

Đề tài nghiên cứu: So sánh giữa sự dùng nước hoặc cồn (alcohol) để lau rửa rún và thời gian rụng rún.

Người nghiên cứu: Jennifer Medves RN,BN
Factulty of Nursing
University of Alberta

Giám thị: Dr. B.O'Brien, PhD
Associate Proffessor,
Faculty of Nursing
University of Alberta
Tel: 492-8232

Mục Đích: Tôi muốn ước lượng thời gian và khám phá dung dịch nào giúp cho cuống rún của trẻ sơ sinh mau khô và mau rụng.

Thủ tục: Nếu bạn muốn tham dự, thì con của bạn sẽ được chọn vào nhóm dùng nước hoặc cồn (alcohol). Người nghiên cứu sẽ hướng dẫn bạn cách lau rửa cuống rún. Bạn sẽ lau cuống rún mỗi khi bạn thay tả cho con cho đến khi rụng rún. Tăm có quấn bông hay vải dùng để lau rún khi con mới sanh và khi con được 3 ngày. Khi bác sĩ cho phép bạn về nhà, chúng tôi sẽ đến thăm bạn tại nhà. Ngày bạn thấy rún của con rụng, xin vui lòng gọi cho chúng tôi hay và chúng tôi sẽ đến lấy vải hay tăm lau rún này về để nghiên cứu. Chúng tôi sẽ xem xét hồ sơ của con bạn bảo sanh viện để biết về trẻ sơ sinh.

Không có gì thiệt hại hay ích lợi trực tiếp gì cho con bạn khi bạn tham dự chương trình này, nhưng những kết quả của nó giúp cho y tá chúng tôi hiểu rõ cách săn sóc nào tốt cho cuống rún mau khô và mau rụng. Bạn tham dự vào sự học hỏi này hay không là do sự quyết định của bạn. Nếu bạn tham dự và sau đó bạn không muốn tiếp tục chương trình này nữa, bạn chỉ cần cho chúng tôi biết. Tham dự hay không đều không có ảnh hưởng gì đến sự chăm sóc cho con bạn.

Tên họ của hai mẹ con bạn sẽ không xuất hiện trên những bài báo hay trong mọi sự thảo luận của sự nghiên cứu này. Sẽ có ký hiệu riêng biệt trên mỗi cây hay vải lau. Bản ghi tên của bạn sẽ được cất kỹ và chỉ có người nghiên cứu giữ hồ sơ của những ai tham dự chương trình này.
Trong tương lai nếu có sự thảo luận về vấn đề này thì người nghiên cứu thì phải có sự chấp thuận của uỷ ban tham vấn của trường đại học.

Đồng Ý: Tôi hiểu rõ về sự nghiên cứu này. Những câu hỏi tôi nêu lên đều được trả lời thoả đáng. Đồng thời tôi cũng có thể liên lạc với người nghiên cứu khi tôi có những thắc mắc. Tên của chúng tôi sẽ được giữ kín và tôi có thể chấm dứt cuộc thử nghiệm này bất cứ lúc nào tôi muốn. Tôi sẽ giữ 1 tờ đồng ý cho riêng tôi. Tham dự vào chương trình này không ảnh hưởng gì giữa sự chăm sóc của bác sĩ và con của tôi.

Ngày và chữ ký của cha mẹ đứa bé

Ngày và chữ ký của người nghiên cứu

Appendix E
Ethical Approval

University of Alberta
Edmonton
Canada T6G 2G3

Faculty of Nursing
3rd Floor Clinical Sciences Building

Certification of Ethical Acceptability for Research Involving Human Subjects

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NAME OF APPLICANT(S): Jennifer Medves, MN Candidate

TITLE OF PROJECT: "A Comparison of Water and Alcohol in Promoting Healing of the Umbilicus and Reducing the Length of Time to Separation of the Umbilical Cord:

The members of the review committee, having examined the application for the above named project, consider the procedures, as outlined by the applicants, to be acceptable on ethical grounds for research involving human subjects.

April 4. 1996
Date

Marion Allen
Marion Allen, PhD
Interim Chair, Ethics Review Committee

ERC 96-079
5005-02-079

Capital Health Authority

Regional Research Administration Office
WMC 5C2.16, 492-1372

Memorandum

NOTICE OF APPROVAL FOR PROPOSED RESEARCH
UNIVERSITY HOSPITALS SITE

Project Title:	A comparison of water and alcohol in promoting healing of the umbilicus and reducing the length of time to separation of the umbilical cord.
Project No.:	M-44
Investigator(s):	Ms. Jennifer Medves
Department:	Faculty of Nursing
Division:	
Address:	CSB 3rd Floor
Phone/FAX:	(403) 639-4041

Supporting documents:

1)	Ethical Approval	April 1996
2)	Study Protocol	Project Summary
3)	Funds:a) Source b) Type	Perinatal Research Centre Grant
4)	Overhead Negotiated	N/A
5)	Account #	
6)	Contract	N/A

Project Approved April 1996

By

Title

Barbara Brady-Fryer
~~Regional Manager~~
Research Administration
Capital Health Authority

Copies to: Dr. D.L. Tyrrell
Department Chair
Finance

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